EUROPEAN MEDICAL WRITERS ASSOCIATION

EMWA Professional Development Programme Brochure

(Last Updated: June 2024)

Introduction

The EMWA Professional Development Programme (EPDP) provides high-quality training for medical writers through workshops and homework assignments. We run the workshops at our twice-yearly EMWA conferences.

All EPDP workshops are approved by the EMWA Professional Development Committee (EPDC) and are given by people with extensive professional experience in the topic. Most are a mixture of lectures and group exercises, with time for questions and discussion.

EMWA workshops usually have a pre-workshop assignment, and all have an assessed post-workshop assignment. If you attend EPDP workshops and successfully complete the assignments you can gain EPDP credits, which can allow you to apply for an EMWA certificate. The element of assessment ensures that EMWA credits represent a real attainment and are a valuable addition to your CV. Credits are added to your personal EMWA professional development record, which you can view online in your EMWA account as long as you remain an EMWA member.

EMWA credits and certificates demonstrate your commitment to continued professional development. However, an EMWA certificate is not an endorsement by EMWA of a person's professional competence – that is, EMWA has not 'certified' the certificate holder. Holding an EMWA certificate does not entitle you to claim that you are 'EMWA certified' or a 'certified medical writer' or similar statement.

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Workshop programmes at EMWA conferences

EPDP workshops are only available at EMWA's twice-yearly conferences. As well as the workshop programme, our conferences offer other opportunities for professional development including seminars, plenary sessions, and symposiums. See the conference pages for information about past and upcoming conferences.

Because we have such a wide variety of workshops, we are unable to run all of them at every conference. When we are scheduling workshops for a conference, we try to ensure the programme covers a broad range of topics and offers a balance of foundation and advanced workshops. We also take account of demand for topics at previous conferences.

Workshops are open only to EMWA conference attendees. Conference registration for non-members includes 1 year's membership of EMWA.

Booking workshops

There is a fee for each workshop, in addition to the conference registration fee (see conference details on the EMWA website).

Workshop places are allocated on a first-come-first-served basis. Some workshops fill up quickly, so it is advisable to register early to avoid disappointment. Booking early will also give you the benefit of the early-bird discount on registering for the conference.

To gain maximum benefit from the conference programme, we recommend you register for a maximum of 5 EPDP credit workshops per conference.

Foundation and advanced workshops

Foundation level workshops are aimed at those who are new to a topic, or who have a moderate level of experience in it. They have a maximum 32 participants and last 3 or 3.5 hours.

Advanced level workshops cover topics that are likely to be of interest to more experienced writers, or deal with foundation level topics in greater depth. There are no formal prerequisites to participate, but leaders will not be able to spend time explaining the basics of the topic to inexperienced participants. The participant profile in the individual workshop description gives details of experience required. Advanced workshops have a maximum of 20 participants and always last 3.5 hours. Some advanced workshops are designated as 'master classes'. These are highly interactive workshops with a maximum of 12 participants.

There are a few all-day workshops in the programme.

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Gaining EPDP credits

Both foundation and advanced workshops can be done to gain EPDP credits. To gain a credit, you must do the pre-workshop assignment (if applicable), attend the workshop, and satisfactorily complete the post-workshop assignment, as described below. If you satisfactorily complete an all-day workshop, you will be awarded 2 credits.

Pre-workshop assignment

After registering for the conference, download the pre-workshop assignment from the EMWA website, complete it (this usually takes up to 2 hours), and submit it to the workshop leader by the deadline given, if applicable. A small number of for-credit workshops do not have a pre-workshop assignment.

If you register for the conference after the deadline for the pre-workshop assignment, you should submit the assignment as soon as you can if you wish to obtain credit. Pre-workshop assignments must be submitted before the workshop. They cannot be accepted after the workshop.

The workshop

To receive credit you must attend the workshop. Participants who miss more than 30 minutes of instructional time (by arriving late, leaving early or leaving the room for a long period) will not be eligible for credit.

Post-workshop assignment

The workshop leader will give you the post-workshop assignment at the end of the workshop or send it to you afterwards.

You must complete the post-workshop assignment to a satisfactory standard, and submit it by the deadline given. It usually takes up to 3 hours to complete a post-workshop assignment, and the deadline is usually about 6 weeks after the conference.

The workshop leader will mark the assignment, let you know whether you have gained a credit, and send you feedback (for example, a model answer or individual comments).

Please note that post-workshop assignments must be your own work. We do not accept joint submissions or submissions based on joint working unless specified by the workshop leader.

Sending your assignments

It is your responsibility to ensure that your assignment reaches the workshop leader. Leaders are asked to acknowledge receipt; if you don’t receive an acknowledgement

within a week, you should contact the leader again to check they have received your assignment. Please follow any special instructions for sending the assignment – for example, a specified email address or email subject line.

Credit records

Credits from each conference are collated by EMWA Head Office and uploaded to members' individual accounts, where they will appear approximately 12 weeks after the conference.

EMWA certificates

You can apply for an EMWA certificate by collecting EPDP credits. You need 8 credits from different workshops to qualify for a certificate. Each EPDP credit can only count once towards 1 certificate. Contact EMWA Head Office to apply for a certificate: email info@emwa.org.

EPDP for-credit workshops are divided into 6 areas of expertise: Drug Development, Language and Writing, Medical Communication, Medical Devices, Medical Science and Professional Techniques.

EMWA certificates are certificates of achievement in continuing professional development. They are not an endorsement by EMWA of a person's professional competence – that is, EMWA has not 'certified' the certificate holder. Holding an EMWA certificate does not entitle you to claim that you are 'EMWA certified' or a 'certified medical writer' or similar statement. Appropriate wording would be: 'I have a foundation [an advanced] certificate from the EMWA professional development programme.

Foundation certificates

An EMWA foundation certificate is awarded for 8 credits from foundation workshops as follows:

- At least 5 foundation workshops in a single area of expertise to qualify for a specialised certificate in that area. The other credits can be obtained from workshops in any of the other areas of expertise.
- Foundation workshops in at least 2 areas of expertise, but no more than 4 workshops per area, for a multidisciplinary certificate.

You may obtain more than 1 foundation certificate after completing the appropriate requirements for each certificate. Certificates list the workshops for which credits have been obtained.

Advanced certificates

An EMWA advanced certificate is awarded for credits in **any** 8 different advanced workshops (these include master classes run for credit). You do not need to have a foundation certificate to register for advanced workshops.

You may obtain more than 1 advanced certificate after completing the appropriate requirements for each certificate. Certificates list the workshops for which credits have been obtained.

Repeating workshops

If you are awarded a credit for a workshop and then repeat the same workshop within 5 years, you will not get another credit. The only circumstances in which this will **not** apply will be if the workshop leader has updated the workshop to the extent that a new outline and abstract have been submitted to the EPDC. In this case, credit will be awarded for the updated workshop.

'Repeating a workshop' will be defined by the core code for the workshop and not by the additions that indicate a minor variation, such as change in workshop leader or workshop title. For example, DDA10 and DDA10a would count as the same workshop.

We cannot accept workshop credits awarded before November 2009 in applications for certificates, because of the way records were kept historically.

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Fees for certificates

An administration fee (currently €100.00) will be charged for issuing certificates. This charge reflects the considerable cost of administering members' training records. The certificate fee replaces the programme enrolment fee that was previously charged.

Workshops currently in the EPDP programme

Currently active workshops are listed below. Click on the workshop title for full details.

The codes in the workshop list tell you which area of expertise the workshop covers and whether it is a foundation or advanced level workshop.

Area of expertise covered by the for-credit workshop	Foundation	Advanced
Drug Development	DDF	DDA
Language and Writing	LWF	LWA
Medical Communications	MCF	MCA
Medical Science	MSF	MSA
Professional Techniques	PTF	PTA
Medical Devices	MDF	MDA

There are also some Soft Skills workshops that are not for credit.

Some topics are covered from different perspectives by different workshop leaders. If you are not sure how to choose between similar workshops, read the workshop abstracts.

Not all workshops are available at all conferences. For further information please refer to the specific conference brochure on the EMWA website.

DDA10a Introduction to the Paediatric Investigation Plan Application

Profile: Medical writers with a working knowledge of clinical drug development and some insight into CMC and nonclinical development. Experience writing IBs or IMPDs would be relevant.

Objective: The workshop will familiarise participants with the EMA's guidance on the Paediatric Investigation Plan (PIP) Application, providing a foundation that will be helpful for writing PIPs.

Content: The PIP is an EMA requirement designed to encourage and regulate the specific development of medicinal products for use in children. The main elements of the workshop will be:

- Background information on the challenges associated with conducting paediatric development programmes and the need for specific regulation
- Objectives of the EMA regulation
- Overview of the format and content of the documentation required for the PIP application.

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Douglas Fiebig

After 8 years in academic research (much of the time spent wading in rivers), Douglas was fortunate to chance upon a job advert that would launch his career in medical writing. It soon became clear to him that, in addition to keeping his feet dry, working as a medical writer was surely the most enjoyable way to earn a living using his scientific and linguistic skills. He has been involved in regulatory medical writing since 1996. Together with two partners, he took the plunge in 2002 and established Trilogy Writing & Consulting, a specialist medical writing company. Many years of writing pre- and post-submission documentation provide the inspiration for his EMWA workshops. Douglas served on the EMWA Professional Development Committee (EPDC) from 2009 - 2013.

DDA14b Periodic Benefit-Risk Evaluation Reports

Profile: This workshop is aimed at medical writers with some experience of assessing drug safety information, and a basic understanding of the overall drug regulatory environment. It will also be useful to writers who are familiar with previous PSUR requirements detailed in Volume 9A but have little or no experience of the new requirements in line with GVP Module VII and the revised ICH E2C. For writers with no previous experience of pharmacovigilance documents it is recommended that they attend the foundation workshop "Introduction to Pharmacovigilance Writing" before attending this workshop.

Objective: Periodic reports are required by the regulatory authorities to provide updated information on the world-wide safety experience with marketed drugs. Medical writers are increasingly being asked to compile such reports on behalf of pharmacovigilance departments. In July 2012, new pharmacovigilance legislation came into effect across the EU updating the required format and content of a periodic safety update report (PSUR). The document now includes efficacy data as well as safety data and has been retitled the 'Periodic Benefit-Risk Evaluation Report' (PBRER). The aim of this workshop is to provide a clear explanation of the requirements of the PBRER in terms of what data need to be included in the document and how they should be presented.

Previous title: Periodic Safety Update Reports
The workshop will briefly discuss the pharmacovigilance requirements for marketed drugs and the place of the PBRER in the drug safety process.

Content: It will discuss in detail the content and method of presentation of the different sections of a PBRER in line with GVP Module VII and the revised version of ICH E2C. There will be particular emphasis on the requirements for reporting of benefit-risk evaluation and how the PBRER relates to other safety documents.

Detailed discussion of submission schedules and the submission process will not be covered in this workshop.

Lisa Chamberlain James

Lisa is a Senior Partner and CEO of Trilogy Writing & Consulting Ltd. Aside from management activities, she leads client projects, with extensive experience in a variety of documents. Lisa has a special interest in writing for the general public and in patient information. Following a PhD and post doc. in Pathology at Cambridge, Lisa began her medical writing career in 2000. Since then she has also been involved in the European Medical Writers Association (EMWA) as a member of the Educational Committee, mentor, leader, and assessor of workshops, and teaches and reviews workshops for the American Medical Writers Association. Lisa holds an EMWA professional development certificate, is a member of TOPRA, DIA, and PIPA, initiated the EMWA PV Special Interest Group, is chair of the Geoff Hall Scholarship Committee, and is a Fellow of the Royal Society of Medicine.

Tiziana von Bruchhausen

Principal Global Pharmacovigilance Writer – Boehringer Ingelheim Pharma
Tiziana has been specialising in pharmacovigilance writing since 2008 and has gained extensive hands-on experience with pharmacovigilance documents and health authorities' assessments. She has developed broad expertise with the implementation of the GVP guideline related to RMPs and PSURs, and with the evolving concept of safety concerns. In her current position at Boehringer Ingelheim, she is responsible for the coordination and preparation of lifecycle pharmacovigilance documents with a focus on DSURs, RMPs, and PSURs; in addition, she is involved in pre- and post-submission activities related to the global strategic planning and health authorities' assessment reports.
Tiziana provides trainings on pharmacovigilance writing for professional education institutions Europe-wide, including EMWA. She is an active volunteer for EMWA, where she was Vice President/President in 2017-2019; she has been chairing the Pharmacovigilance Special Interest Group (SIG) since 2017, and since May 2021 she has been on the Committee of the Communicating with the Public SIG.

DDA18a Medical Writing for Healthy Volunteer Studies

Profile: This workshop is for medical writers who would like to learn more about writing the documents needed for clinical trials conducted with healthy volunteers rather than patients (such as Phase 1, thorough QT, and bioequivalence studies). Participants should have basic knowledge of healthy volunteer study objectives and design (participants who do not have this knowledge should first take Workshop DDF39 An Overview of Healthy Volunteer Studies) and some experience in writing key clinical trial documents (informed consent forms, protocols, clinical study reports).

Objective: Healthy volunteer studies make up a large proportion of studies in most clinical development programmes. Medical writers need to understand how these studies differ from clinical trials in patients and how the differences affect the documents required for these studies. After attending this workshop, the participant will understand the unique structural and content requirements of documents related to healthy volunteer studies.

Content: This workshop will cover the following topics for healthy volunteer studies:

- Key regulatory guidance documents
- Protocols
- Informed consent forms
- Clinical study reports

Note: Phase I studies in patients will not be covered.

Anne McDonough

Anne is a medical writer with over 25 years of experience in a wide variety of therapeutic areas for clients ranging from emergent biopharma companies to multinational corporations. She has worked in a number of research roles (writing, clinical science, operations, compliance, and training) and has settled on medical writing as the most enjoyable of them. Her experience includes dozens of healthy volunteer studies (PK/PD, microdosing, thorough QT, food effect, bridging, etc.). Anne writes across the continuum of clinical research from operational documents to clinical study reports, nonclinical and clinical CTD modules, and manuscripts. She has also worked with nonprofit organisations and academia on conference reports, manuscripts, clinical support tools, and training and evaluation materials.

DDA19 Pharmacokinetic and Pharmacodynamic Modelling: an Overview for Medical Writers

Profile: Participants should be familiar with the drug development process and have an understanding of basic pharmacokinetics.

Objective: After completing the workshop, participants will have an understanding of the strategic role PK/PD modelling plays in drug development. In addition, they will gain an appreciation of how modelling can influence the claims that can be made on the drug label. They will be better placed to discuss modelling issues within projects, and to incorporate modelling outcomes into reports and regulatory documents.

Content: The rationale for modelling in drug development is presented, along with the regulatory view. Different modelling techniques (compartmental, population, pharmacokinetic/pharmacodynamic [PK/PD], physiologically based (PBPK) are discussed in terms of their principles, their role within a drug development

programme, and common terms used in their execution. This is illustrated with examples from the literature and the presenter's personal experience. How modelling output can influence the claims made on the drug label will be discussed. The workshop consists of modules interspersed with individual and group learning tasks.

Graham Blakey

Graham had been investigating the clinical pharmacology of new drugs and novel formulations for over 20 years. He is CEO of PharmaKinetic limited a CRO providing pharmacokinetic and clinical pharmacology expertise to aid drug development. Over the course of his career he has been involved in the transition of several new chemical entities from discovery into humans. He is experienced in a number of PK methodologies and has used these across the drug development spectrum. Graham is an advocate of creative and efficient clinical study design and has applied these principles to many global drug development projects in several therapeutic areas. His skills have involved him in various patent cases where he has acted as an expert witness in several jurisdictions.
Graham has developed professional PK training courses for both experts and non-experts working in the pharmaceutical and bioscience sectors. Additionally, he has provided PK teaching on a number of undergraduate and postgraduate degree courses. Graham is a pharmacist, with an MSc in Clinical Pharmacology from the University of Glasgow and a PhD from the University of Manchester.

DDA1a Writing Global Submission Dossiers using the Common Technical Document

Profile: The course is intended for medical writers with little or no experience of writing clinical submission dossiers although participants should be familiar with the clinical development process and have had some experience of writing clinical study reports.

Objective:

- To introduce participants to the preparation of clinical submission dossiers according to the CTD
- To convey general principles and process of summary writing
- To facilitate understanding of the limits of the available regulatory guidance

Content:

- Development and background of the CTD
- Purpose and types of clinical summary documents
- CTD Module 2.5 (Clinical Overview)
- CTD Module 2.7 (Clinical Summary)
- Integrated summaries of efficacy and safety for the USA

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James Visanji

James holds a PhD in Medicine from the University of Manchester, Masters in Clinical Genetics from the University of Sheffield, Chartered Linguist status from the Chartered Institute of Linguists, and the European Medical Writers Association Nick Thompson Fellowship.
After postdoctoral work at Istituto Europeo di Oncologia, James started his medical writing career in 2006. Based in Frankfurt, he is currently Associate Director of Clinical Writing at Certara Insight, and was previously Medical Writing Manager at Trilogy Writing, and Deputy Director at Accovion (now Clinipace).
James focuses on clinical and regulatory documentation, in particular, submission dossiers and subsequent regulatory interactions. James has been training medical writers and physicians since 2012, and claims to get his biggest buzz from making the next generation of writers as effective as possible, as quickly as possible.

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Content:

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- Purpose and types of clinical summary documents
- CTD Module 2.5 (Clinical Overview)
- CTD Module 2.7 (Clinical Summary)
- Integrated summaries of efficacy and safety for the USA

Claire Dyer

Claire is a medical writing manager at Trilogy Writing and Consulting. She worked in pharmaceutical and academic research before and after her PhD in immunology and oncology. Claire has worked within the pharmaceutical and CRO industry in a number of clinical and medical roles including medical information and sales/marketing. After leaving the big smoke in London, she decided on a career in medical writing. Claire has been a medical writer since 2007 and joined the trilogy

team in 2013. She has a wide range of experience and a particular interest in regulatory documents covering various therapeutic areas.

DDA20 Risk Management Plans: Challenges and insights

Profile: Aimed at medical writers with some experience of writing risk management plans (RMPs) or other safety documents (e.g. Periodic Safety Update Reports), or who have attended the foundation workshop on RMPs (the latter may be helpful for those with no experience of RMPs). Participants may also find the workshop "Introduction to Pharmacovigilance writing" (DDF32) helpful.

Objective: To learn about the regulatory requirements and the main changes introduced by the revision of the RMP guidance and template (expected in January 2017). At the end of the workshop, participants will be able to identify the right format and content for each section and deal with some major challenges of the new RMP format.

Content: This workshop will provide an overview of the changes introduced by the revision of the Good Pharmacovigilance Practice (GVP) module V on Risk Management Systems, particularly focusing on the RMP format. Participants will learn how to choose the right format for RMPs in different scenarios. A brief overview of the structure and contents of the RMP according to the revised GVP Module V will be provided. Major challenges of the new format will be explored in exercises. Particular emphasis will be given to the new definition of important risks, to common pitfalls when updating existing RMPs written in the old format, and to the summary of the RMP for the lay public.'

Tiziana von Bruchhausen

Principal Global Pharmacovigilance Writer – Boehringer Ingelheim Pharma
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Tiziana provides trainings on pharmacovigilance writing for professional education institutions Europe-wide, including EMWA. She is an active volunteer for EMWA, where she was Vice President/President in 2017-2019; she has been chairing the Pharmacovigilance Special Interest Group (SIG) since 2017, and since May 2021 she has been on the Committee of the Communicating with the Public SIG.

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DDA24a Clinical Study Reports in Oncology

Profile: This workshop is intended for medical writers who have already some experience in the writing of clinical study reports (CSRs) but no experience in oncology. Participants should have a general understanding of clinical study designs, of the guidance provided by ICH E3, and should be familiar with basic clinical trial statistics.

Objective: This workshop aims to provide a systematic overview of what is different about oncology CSRs. Having attended the workshop, Medical Writers should have an understanding of key oncology concepts and should be able to apply these to the writing of the different report sections.

Content: The workshop will introduce key oncology concepts and will outline how these concepts inform the writing of the CSR. We will go through the report sections (following ICH E3). Topics discussed along the way will include:

- Patients with cancer: diagnosis, treatment modalities, disease progression
- Clinical studies in oncology: study design; interim vs. final analysis; trial committees (Data Monitoring Committee, Central Independent Review)
- Drugs in oncology: principles of dose finding, treatment schedules, dose reduction / escalation, management of side effects
- Efficacy: assessment of tumour response – RECIST; central independent review vs. investigator assessment of tumour imaging; time-dependent endpoints, especially progression-free survival, time to progression, overall survival; importance of censoring rules
- Safety: CTCAE grading system, Dose Limiting Toxicities and Maximum Tolerated Dose, MedDRA and Standard MedDRA Query, the concept of "adverse events of special interest"

Thomas Schindler

Thomas M Schindler studied biology and linguistics in Germany and the UK, obtained a PhD in molecular physiology, and did postdoctoral research in the UK. Thereafter, he became an editor of popular science books in biology, geography, and astronomy. He then turned to medical writing and has now gained some 25 years of experience in both medical affairs and regulatory medical writing including the preparation of all documents for marketing authorization applications around the globe. He founded and established the medical writing function at Boehringer Ingelheim and has recently headed the Innovation Medical Writing Group focussing on lay communication, good graphics development, video creation and AI-driven writing.

He was a member of the TransCelerate Return of Results work stream, is contributing to the Good Lay Summary Practice initiative and the PFMD Plain Language Summary guidance.

Kirsten Herbach

Kirsten is a food engineer with a PhD in natural sciences. In 2007, she decided to become a medical writer and joined Boehringer Ingelheim, where she held several medical writing and team lead positions. In 2020, Kirsten joined Granzer Regulatory Consulting & Services as Senior Medical Writer/Senior Consultant. Over the years, Kirsten has planned, written, and managed a wide range of regulatory documents in various therapeutic areas and indications.

DDA26 Post-submission Pharmacovigilance Writing Interactions with Authorities and Impact on RMPs and PSURs

Profile: Medical writers who would like to gain advanced knowledge about RMP and PSUR assessment processes and the role of the medical writer after document submission in Europe. Participants without hands-on experience with RMPs and PSURs should in advance attend the courses DDA14a, DDF30, or DDF32.

Objective: This workshop will explore medical writing tasks from first submission onwards and throughout the lifecycle of the medicinal product. Participants will learn how to handle authority requests and parallel RMP and PSUR preparation.

RMPs are prepared for new marketing applications. Within the authorisation procedure and also later on, throughout the lifecycle of the medicinal product, the RMP may have to be updated to always reflect the most current knowledge on the product's risk profile. After marketing authorisation, PSURs will be prepared. The assessment of PSUR and RMP may often impact both documents and requests may have to be addressed at the same time and within short timelines.

The medical writer provides guidance to the product teams and plays a central role throughout the submission and assessment procedures of RMPs and PSURs.

Objective: The workshop will cover a variety of pharmacovigilance writing activities between RMP submission and closing sequence (e.g., responses to authority questions, RMP updates),will explore PSUR evaluation procedures, and the impact of PSUR assessment on the RMP (e.g., addressing assessment report requests in the next PSUR and/or RMP).

We will guide participants through possible scenarios and address typical questions and pitfalls.

Stefanie Rechtsteiner

Stefanie has been working in the pharmaceutical industry for many years, starting in biotech, moving on to marketing/sales, until she specialised in safety writing from 2011 onwards. She has extensive hands-on experience on DSUR, RMP, AddCO, and

PBRER writing and currently works as a principal pharmacovigilance writer at Boehringer Ingelheim. Stefanie joined EMWA in 2011 and has offered various workshops on safety writing at EMWA over the past years.

Tiziana von Bruchhausen

Principal Global Pharmacovigilance Writer – Boehringer Ingelheim Pharma
Tiziana has been specialising in pharmacovigilance writing since 2008 and has gained extensive hands-on experience with pharmacovigilance documents and health authorities' assessments. She has developed broad expertise with the implementation of the GVP guideline related to RMPs and PSURs, and with the evolving concept of safety concerns. In her current position at Boehringer Ingelheim, she is responsible for the coordination and preparation of lifecycle pharmacovigilance documents with a focus on DSURs, RMPs, and PSURs; in addition, she is involved in pre- and post-submission activities related to the global strategic planning and health authorities' assessment reports.
Tiziana provides trainings on pharmacovigilance writing for professional education institutions Europe-wide, including EMWA. She is an active volunteer for EMWA, where she was Vice President/President in 2017-2019; she has been chairing the Pharmacovigilance Special Interest Group (SIG) since 2017, and since May 2021 she has been on the Committee of the Communicating with the Public SIG.

DDA27 Medical Writing for Biosimilars

Profile: Participants should be familiar with the drug development process and have an understanding of basic pharmacokinetics and statistics. In addition, participants should have experience with clinical study reports and regulatory submission dossiers.

Objective: After completing the workshop, participants will have an understanding of the differences between biosimilars and NBE development. In addition, they will understand how these differences influence the development of clinical documents. They will appreciate the challenges they might face when working in this relatively new field of Medical Writing.

- General overview on biosimilars clinical development
- Dealing with biosimilars clinical study reports (Phase I and Phase III)
- Dealing with the clinical documents of a biosimilars submission dossier

Sabrina Stöhr

Sabrina is a Regulatory Medical Writer with 10+ years of experience in clinical development. She has been involved in document writing across all stages of development and in various indications (e.g. oncology, inflammatory diseases, biosimilars). She has experience in the development of Briefing Documents directed to the EMA and FDA as well as other regulatory interaction and meetings. Following a PhD in human genetics and a postdoc in cancer research, she pursued an

advanced training in clinical research before joining the pharmaceutical industry. Sabrina is also an experienced EMWA workshop leader.

Katharina Brauburger

Katharina is a biologist by training. She received her doctoral degree working on protein biochemistry and molecular tumour biology. To start her regulatory medical writing career, she joined Boehringer Ingelheim as a Medical Writer. Afterwards Katharina joined the Regulatory Writing & Submissions team of Sandoz, a Novartis division and continued working as a Regulatory Medical Writer, writing and managing submission documents for biosimilar as well as innovative medicine submissions. In 2021, she continued her medical writing career at Merck. Over the years, Katharina has been involved in writing and managing documents across various stages of clinical development and across various therapeutic areas and indications, including both biosimilar and innovative medicine development programs.

DDA28 The Investigational Medicinal Product Dossier: Gateway to Introducing New Drugs in the European Union

Profile: The Investigational Medicinal Product Dossier (IMPD) is an important part of the clinical trial application (CTA) which is submitted to the EMA for approval of clinical trials of investigational medicinal products (IMPs) in the EU. Those who stand to benefit from this workshop are regulatory personnel and medical writers in the pharmaceutical industry, CROs, and medical writing agencies who are involved in preparing regulatory documentation – especially documents pertaining to the chemistry, manufacturing, and quality control (CMC) of IMPs.

Objective: Participants of this workshop will get an ***overview*** on the individual parts of the IMPD, as well as details of the relevant source documents and submission requirements and the medical writer's role in the preparation of the dossier. Additionally, the workshop aims to inform participants on Blockchain technologies, implemented in Supply-Chain-Management, in clinical trials.

The IMPD includes summaries of information related to the quality, manufacture and control of the IMP, data from non-clinical studies and from its clinical use. An overall risk-benefit assessment, critical analyses of the non-clinical and clinical data in relation to the potential risks and benefits of the proposed study also have to be part of the IMPD.

Content: The main focus of the workshop will be to clarify the medical writer's role in the selection, assembly, and summary of relevant source documents for drafting a full or simplified IMPD for medicinal drug products, with a strong emphasis on the chemistry, manufacturing, and quality control (CMC) components of these.

Furthermore, the workshop aims to educate participants on recent Supply-Chain-Management developments in clinical trials, with focus on Blockchain technologies, required for the IMPD assembly.

The workshop is planned to be interactive and will include discussion of participants' questions submitted in their pre-workshop assignments, where relevant. There will also be a handful of exercises carried out during the workshop to encourage overall participation.

Carola Krause

Based in Potsdam, Germany, Carola Krause has been offering a professional biomedical writing consultancy service to the pharmaceutical industry since 2016. Carola is a postdoctoral molecular cell biologist with hands-on experience in basic and pharmaceutical research and development. Her multidisciplinary background in academic and pharmaceutical project management and clinical trial coordination provides her with key insights into all phases of the drug development process and its regulatory requirements. She has 15 years of experience in biomedical communication and has attended EMWA workshops since 2014. Carola is the chair of EMWA's Creative team, co-founded the Sustainability Special Interest Group and has served as EMWA's (Vice)President from 2020–2022.

Satyen Shenoy

Satyen is a medical writer operating his consultancy, Describe, from Germany. Satyen comes from a background in biomedical research having spent over a decade in academia as well as the pharma industry, in India, the USA, and Germany. He has worked on various research projects, ranging from gene-bashing to stem cell differentiation to anticancer drug discovery. In 2010, Satyen got his first taste of medical writing while drafting a manuscript for a large-scale vaccine trial conducted by a multinational pharma company. Since then, he has found his true calling, has traded his labcoat for a Macbook Pro, and pursued a career in medical writing. With an intention of being a part of the medical writing profession in Europe, Satyen moved to Germany in 2015 to open his little scriptorium.

Satyen has been an EMWA member since 2010. He is a volunteer with the Freelance Business Group (FBG), as a Freelance Advocate in the past and as Chairperson of the FBG subcommittee since May 2018. Besides promoting effective scientific communication, Satyen is also keenly involved in the development of freelance medical writing as a profession in Germany and Europe

DDA29 Medical Writing for Non-interventional and Database Studies

Profile: This workshop addresses writers dealing with or interested in documents for non-interventional (observational) studies for epidemiology, real-life safety and efficacy, health economics, and quality of life. This is a development of the DDA 9 workshop with an emphasis on the new opportunities to design studies using existing clinical databases. Participants should have at least 2 years of medical writing experience with study related documents (e.g. protocol, CSR, scientific publication).

Objective: This workshop provides you with the definition of non-interventional studies, how they differ from randomized controlled clinical trials (RCT) and what is the regulatory background for these differences. The diversity of types of non-interventional studies will be explained, with special emphasis on recent study designs using existing clinical databases instead of study specific databases. It will be explained how documents for non-interventional studies are prepared by medical writers (in particular, protocols and study reports), and how writing differs from RCTs.

Content: What is non-interventional research. Definition of non-interventional studies. Scientific Goals of Non-Interventional Studies. Different Designs of Non-interventional Studies. Use of Databases in Non-interventional Studies. Are Non-Interventional Studies Scientifically Valid? Documents for Non-interventional Studies, similarities and differences to RCT documents (SAP, Protocols, ICF, Reports, Publications, Transparency Reporting). Specific ways to describe Non-interventional Study design and study results. Differences in discussion and interpretation of the data compared to RCTs.

Thomas Wagner

Thomas is a biologist by training and was working hard to unravel the mysteries of the brain using his own brain and such obscure things as glass needles, fluorescent dyes and white powders called neurotransmitters. However, in order to avoid going mad himself, he quit university and started his medical writing career in 1999 with the CRO Kendle in Munich. In 2002 he changed to big pharma and worked for Lilly Deutschland GmbH, mainly writing on Phase III-IV projects, including observational studies. Still working in the area of madness he mostly tackled psychiatry, quality of life, and red tape in the position of Group Leader Scientific Communications Europe for Neurosciences at Eli Lilly & Co. To avoid getting entangled too much he then changed in 2009 to the other side of the fence now working as a service provider and consultant for Trilogy Writing & Consulting as Medical Writing Manager. In 2015 Thomas moved to the headquarters of Merck Healthcare KGaA in Germany and is responsible for all regulatory medical writing documents from Phase I to post-marketing studies in the “beyond oncology” area; including the setup of a MW hub in Bangalore/India.

EUROPEAN MEDICAL WRITERS ASSOCIATION

DDA35 Safety and Contraception information for the Informed Consent

Profile: This workshop is ideal for medical writers with experience in creating documents for regulatory or non-specialist readers. It is especially beneficial for medical writers involved in developing informed consent materials for potential study participants. Medical writers who may need to produce written information in lay language about the safety and contraceptive aspects of a drug in clinical research will find this workshop particularly useful. Ideally participants understand an investigator brochure and of a clinical trial protocol.

Objective: The purpose of the Informed Consent Form (ICF) is to provide potential study participants with a clear summary of the risks involved in the study. This information should be written in easy-to-understand language so that participants can make an informed decision whether to participate in a clinical trial. It is essential for project and trial teams in clinical research to regularly update this information. Medical writers with expertise in regulatory and lay language writing can contribute valuable skills in developing and updating the risk information. The goal of this workshop is to help participants gain a comprehensive understanding of the language, templates, processes, and tools needed to effectively develop and update safety and contraception information in lay language for informed consent purposes.

Content: The safety and contraception content in an ICF will be presented and discussed. There will be particular emphasis on the development of reproducible and harmonized side effect and contraception information. Other topics include recommended lay language terminology, tools, and process considerations.

Julia Moffitt

Julia is an experienced medical writer with over 25 years of experience in academia. She recently joined Boehringer Ingelheim in July 2022 as an Associate Director of Lay Language & New Media. Julia specializes in writing regulatory documents in lay language, including Brief Summaries of Clinical Trial Protocols, Lay Protocol Synopses, and Lay Summaries of Clinical Trial Reports. She has also coordinated the development of the ICF Safety Section template and processes for development of the Safety Section of the ICF. Julia's expertise extends to data science, as she holds a certificate from MIT and is currently working on a project to automate certain aspects of medical writing using Artificial Intelligence. Julia is a member of the American Medical Writers Association and member of the MidAmerica Medical Writers leadership team serving as the coordinator of Iowa Medical Writers networking events.

EUROPEAN MEDICAL WRITERS ASSOCIATION

Cornelia Weiss Haljiti

Cornelia Weiss-Haljiti is an Expert Medical Writer and a biochemist by training with a PhD in endothelial cell biology. For 10 years, she worked as a scientist leading projects and laboratories in academia, biotech, and pharmaceutical industry. Cornelia developed expertise in the discovery and validation of targets, drugs, and biomarkers.
In 2012, Cornelia joined Boehringer Ingelheim Pharma GmbH & Co. KG. to become a Medical Writer. She wrote regulatory documents across all phases and therapeutic areas. She holds the EMWA foundation and advanced certificate. Over time she became particularly interested in plain language writing, graphics, and design. She was the design lead of a digital platform to share lay summaries of study results with the public. Currently she leads and represents Informed Consent activities by the Lay Language & New Media Team, a specialized medical writing team within Boehringer Ingelheim.

DDA2b Medical Writing Between Dossier Submission and Drug Approval

Profile: Medical writers with knowledge of MAA or NDA preparation who are interested in expanding their knowledge of authority review processes and the role of medical writing after dossier submission in Europe and the US.

Objective: While the Common Technical Document harmonises the structure of regulatory documents submitted to the European EMA and the US FDA for marketing approval, the review processes leading to the decision on whether to approve or not still differ markedly between the two authorities. In both cases, though, the demand for medical writing skills in the broadest sense (linguistic, scientific, organisational, diplomatic) can be high. The objective of this workshop is to familiarise participants with the post–submission review processes of these two authorities and illustrate the pivotal role medical writers can play in helping to optimise a sponsor's chances for obtaining a successful drug approval.

Content: The workshop will navigate you through the post–submission review processes you can expect to encounter, and through the numerous medical writing activities that can arise during EMA and FDA reviews of a submission dossier (e.g., drafting responses to the authority's questions, preparing safety updates and NDA amendments, writing briefing documents, organising and preparing presentation materials for CHMP Oral Explanations and FDA Advisory Committee meetings). The workshop illustrates salient points and potential pitfalls by recalling personal experiences working on a European–US approval team. The workshop exercise focuses on how FDA and sponsor can differ in their interpretations of the same data, which will give participants some insight into the FDA Advisory Committee hearing process and into the preparations that need to be made for it by the sponsor.

Douglas Fiebig

After 8 years in academic research (much of the time spent wading in rivers), Douglas was fortunate to chance upon a job advert that would launch his career in medical writing. It soon became clear to him that, in addition to keeping his feet dry, working as a medical writer was surely the most enjoyable way to earn a living using his scientific and linguistic skills. He has been involved in regulatory medical writing since 1996. Together with two partners, he took the plunge in 2002 and established Trilogy Writing & Consulting, a specialist medical writing company. Many years of writing pre- and post-submission documentation provide the inspiration for his EMWA workshops. Douglas served on the EMWA Professional Development Committee (EPDC) from 2009 - 2013.

DDA3 The CTD Clinical Summary

Profile: This workshop is aimed at writers with experience in writing clinical study reports but who are new to writing CTD Clinical Summaries.

Objective: The purpose of this workshop is to look at creating the optimal CTD Clinical Summary that achieves its purpose. On completion of the workshop package, participants should be able to approach writing a CTD Clinical Summary with a better understanding of the expectations of a Regulatory Authority Assessor.

Content: The workshop will begin with a brief presentation on what the CTD Clinical Summary is and where it fits in to the overall clinical dossier. This will then be followed by a review of the Clinical Summary structure and the important points within each section. This will then be followed by a review of some example data packages and a group discussion will take place to decide the best way of presenting the data. Finally, there will be a review and summary of the key messages to bear in mind when writing a CTD Clinical Summary.

Debbie Jordan

Debbie has been working in the pharmaceutical industry for over 30 years in both pharmaceutical company and CRO environments. She has worked as a data assistant, CRA and project manager, before moving into medical writing. Twenty years ago she set up her own medical writing company and now works on all aspects of medical writing from clinical development programmes and regulatory packages through to marketing and conference material. Debbie also provides training in medical writing and associated topics to a variety of organisations. Debbie has served on the Executive Committee of EMWA in the past and was a key member of the CORE reference working group.

DDA31 Orphan Medicinal Drug Products

Profile: This workshop will benefit medical writers who have an interest in the clinical development of orphan medicinal products, and who are familiar with the European Medicines Agency marketing authorisation application (MAA) procedures. Prior attendance to DDF13 Basic Concepts of Study Design in Clinical Development would be helpful but is not essential.

Objective: To provide participants with an understanding of how to prepare the scientific part of an orphan designation application and to recognise strategies used in clinical development of an orphan medicinal product.

Content: Orphan medicinal products are intended to treat rare diseases, and the pharmaceutical industry are eligible for a number of incentives if they develop these products. However, a medicinal product cannot be granted orphan designation unless orphan designation is approved by the European Commission, and an approval of orphan designation is not a guarantee for a successful marketing authorisation. Clinical development of orphan medicinal products is often complex because rare diseases are poorly characterised and under-researched at the time of development, and only affect a small percentage of the population. This workshop will provide an overview of orphan medicinal products, rare diseases and incentives; provide an overview of the orphan designation procedure; provide guidance on how to prepare a comprehensive orphan designation application (scientific part); and provide strategies for clinical development in orphan medicinal products. As protocol assistance is an incentive granted for orphan designation, an overview of the procedure will also be covered.

Cheryl Roberts

Cheryl is currently the head of the European medical writing group for BioMarin, and specialises in medical writing for serious and life-threatening rare diseases. She joined the pharmaceutical industry in 2001 in drug development, and continued in positions in medical editing and medical writing in both the pharmaceutical and consultancy industry. She holds a degree in Medical Biology and a Masters in Neuroscience.

DDA32 Writing Development Safety Update Reports

Profile: This workshop is for medical writers who would like to obtain knowledge about the Development Safety Update Report (DSUR). Participants should have some experience of collection and analysis of safety data, and an understanding of safety monitoring during clinical trials. Participants without this knowledge or without experience in safety/pharmacovigilance writing should in advance attend the course DDF32.

Objective: This workshop will provide participants with a comprehensive overview and the knowledge needed to write a DSUR. Starting with the DSUR's regulatory

background, purpose, and goal, the workshop will guide participants through the DSUR requirements, document content, the preparation and writing process.

Content: Since 2011, DSURs are required in the ICH region for all marketed drugs or drugs under development for which clinical trials are ongoing. The aim of this workshop is to explain what the DSUR is, when it needs to be written (and when possibly not), which data and information need to be included and how to present them. It also provides guidance on the writing and project management process, taking into account that the DSUR is a document that requires an interdisciplinary and well-organised team effort within challenging timelines. Concise as per guidance, with a clear and logical structure, the DSUR nevertheless has some pitfalls in store that are also discussed in this workshop. To bring life and colour to the theory, all of this is illustrated with examples from the daily practice of preparing and writing DSURs.

Stefanie Rechtsteiner

Stefanie has been working in the pharmaceutical industry for many years, starting in biotech, moving on to marketing/sales, until she specialised in safety writing from 2011 onwards. She has extensive hands-on experience on DSUR, RMP, AddCO, and PBRER writing and currently works as a principal pharmacovigilance writer at Boehringer Ingelheim. Stefanie joined EMWA in 2011 and has offered various workshops on safety writing at EMWA over the past years.

DDA33 Estimands: A 360-degree Approach for Medical Writers

Profile: The workshop is for MWs working in the CRO or pharma environment, who have written at least one or reviewed several clinical study protocols (CSPs). Managers of MW groups will also benefit from understanding estimand-driven processes that impact business and wider operational considerations.

Objective: The workshop is designed to facilitate interpretation of the International Council for Harmonisation (ICH) guideline E9(R1) 2019, which drives estimand development into trial design, and to clarify the MW's role and responsibilities in relation to that of medical experts and statisticians in ensuring that estimands are considered as part of a proactive cross-functional approach to writing the CSP. At the end of the workshop, attendees should understand the concept of estimands and their impact on CSPs and other study-level documents, and have acquired the knowledge and skills to author or review CSPs that include estimands.

Content: Inclusion of estimands into confirmatory clinical trials is mandated through ICH guidance E9(R1) 2019, which is targeted at statisticians but also needs to be understood by MWs who often lead on CSP design and development. A general

process will be described to enable MWs to develop and describe estimands at a level appropriate for the CSP. Open access resources will be demonstrated and some illustrative examples will be presented to clarify statistical concepts associated with estimands. To enhance learning, attendees will work on examples provided during the workshop. Detailed statistical analysis methods will not be covered in the workshop.

Sam Hamilton

Sam Hamilton is a postdoctoral virologist, with 28 years in clinical and regulatory medical writing and leadership roles in the pharmaceutical industry. Sam has a special interest in public disclosure of clinical-regulatory documents as Chair of the EMWA-AMWA group who delivered the open-access www.core-reference.org in May 2016. Sam is long-time supporter of EMWA serving in various roles over 15 years, notably as Freelance Advocate; Editorial Board member for Medical Writing (MEW); Workshop Leader; Expert Seminar Series (ESS) Chair; and Vice President and President. Sam was elected an EMWA Nick Thompson Fellow in 2018 for her services to the Association. Sam is currently MEW Section Editor for the "Regulatory Public Disclosure" Section, and Chair of The CORE Reference Project.

Alison McIntosh

Alison has been a medical writer for the pharmaceutical industry for almost 30 years, and has written extensively for regulatory authorities, and other audiences. She became a medical writer after completing her PhD and a further 5 years of postdoctoral research in molecular virology. Her wealth of experience encompasses many different types of documents including manuscripts, book chapters, and clinical and scientific abstracts, as well as clinical study reports, investigator brochures and other regulatory documents. Alison has been a workshop leader since 2001 and is a section editor for the EMWA journal Medical Writing as well as a member of the EMWA Special Interest Group on regulatory public disclosure. She also serves as a committee member of the EMWA CORE Reference Project.

DDA34 Briefing Documents – The communication channel to Health Authorities from a Medical Writer's perspective

Profile: Regulatory Medical Writers involved in Briefing Document development or interested in this highly strategical document that shapes a product's clinical development program. Experience in clinical study protocol writing or previous attendance of the EMWA workshop 'Basic Concepts of Study Design in Clinical Development' (DDF13), is recommended.

Objective: Medical Writers play a key role in aligning the cross-functional input during briefing documents development. Attendees will acquire knowledge of the

goals, interaction types and structure of Briefing Documents directed to the EMA and FDA, as well as strategical consideration to effectively lead and coordinate this multidisciplinary effort.

Content: Participants will get a deep dive into Briefing Documents:
- Health Authority interactions requiring Briefing Documents
- Formats, structure, and content of Briefing Documents (EMA, FDA)

A step-by-step guidance for Medical Writers to support the Briefing Document development will be provided:
- Writing support (e.g. defining the list of questions and the Sponsor's position)
- Project management support: setting up a routemap, coordinating cross-functional interactions, understanding timings, and managing and optimizing the production steps.

Challenges and pitfalls that might be encountered and how to overcome them will be discussed.

Sabrina Stöhr

Sabrina is a Regulatory Medical Writer with 10+ years of experience in clinical development. She has been involved in document writing across all stages of development and in various indications (e.g. oncology, inflammatory diseases, biosimilars). She has experience in the development of Briefing Documents directed to the EMA and FDA as well as other regulatory interaction and meetings. Following a PhD in human genetics and a postdoc in cancer research, she pursued an advanced training in clinical research before joining the pharmaceutical industry. Sabrina is also an experienced EMWA workshop leader.

Katrin Zaragoza Doerr

Katrin is Senior Principal Medical Writer at Merck S.L.U., overseeing and supporting the development of regulatory documents during clinical development. She has developed Briefing Documents directed to the EMA, FDA and CDE in multiple indications. Her medical writing expertise includes the regulatory (7+ years), medcomms and basic research arena, both as freelancer and employee. With a PhD and 10 years experience as a molecular medicine scientist, she joined the pharmaceutical industry in 2011. Katrin's experience in clinical operations further complements her overview of clinical research and associated documents.

DDA5 The CTD Clinical Overview

Profile: This workshop is aimed at writers with experience in writing study reports but who are new to writing Clinical Overviews for the Common Technical Document (CTD).

Objective: The purpose of this workshop is to look at creating the optimal CTD Clinical Overview that achieves its purpose. On completion of the workshop package, participants should be able to approach writing a CTD Clinical Overview with a better understanding of the expectations of a Regulatory Authority Assessor.

Content: The workshop will begin with a brief presentation on what a Clinical Overview is and how it fits into the dossier as a whole. This will then be followed by an overview of the Clinical Overview structure and the important points within each section. Finally there will be some pointers about what a regulatory reviewer wants from a Clinical Overview. Participants will then have the opportunity to take part in a group exercise drafting a Product Development Rationale section based on information provided in the workshop.

Debbie Jordan

Debbie has been working in the pharmaceutical industry for over 30 years in both pharmaceutical company and CRO environments. She has worked as a data assistant, CRA and project manager, before moving into medical writing. Twenty years ago she set up her own medical writing company and now works on all aspects of medical writing from clinical development programmes and regulatory packages through to marketing and conference material. Debbie also provides training in medical writing and associated topics to a variety of organisations. Debbie has served on the Executive Committee of EMWA in the past and was a key member of the CORE reference working group.

DDA7b Serving Two Masters: Comparing and Contrasting US and EU Regulatory Submissions and Processes

Profile: This workshop is intended for medical writers who wish to learn more about the global regulatory environment for pharmaceuticals.

Objective: The purpose of this workshop is to introduce medical writers to the regulatory and cultural underpinnings of differing processes applied to the preparation, submission, review, and approval of regulatory submissions for pharmaceuticals to EU and US licensing authorities. On completion of the workshop, attendees should better understand the way the agencies operate and the requirements (as stated in the regulations and implicit in industry best practices) for preparing a successful dossier.

Content: There is an internationally agreed format for the presentation of an application dossier for a marketing authorisation for a pharmaceutical product: the Common Technical Document (CTD). It is accepted by all ICH member countries; however, this does not mean that the way in which reviewers approach the assessment is the same, or that the processes for submission, review, and approval

are identical. In particular, there are significant differences between the way data are summarised and the approach taken by European reviewers compared to that taken by their counterparts in the USA. In addition, the Sponsor-Regulator interfaces and processes are quite different. While some of these differences may ultimately evolve to a state of commonality, others likely never will.

Participants will be introduced to the origins of drug regulations, and will review some of the labyrinthine procedures associated with preparing, filing, and defending a licensing application. Cultural and practice differences and similarities between the EU and the USA will be explored. This workshop does not cover the regulatory requirements for medical devices or vaccines.

Art Gertel

Art has a background in neurophysiology and behavioural medicine. As an independent consultant, he specialises in regulatory strategy, Data Safety Monitoring Board management, medical writing, and bioethics. Art has held senior posts at a number of companies including Schering-Plough/Merck, Hoffmann-LaRoche, TFS, and Quintiles, and headed departments responsible for medical writing, publications, project management, and regulatory affairs. He also served as a Senior Research Fellow with the Centre for Innovation in Regulatory Sciences (CIRS). Art has extensive teaching experience and has presented to professional organisations (e.g. EMWA, AMWA, DIA), and corporate and academic audiences, worldwide. He spent 2 years heading Clinical Operations for an eDC 'dot.com' company, and has been active in CDISC since its inception. He served as Chair of the Global Ethics and Regulatory Initiative (GERI) of the Alliance for Clinical Research Excellence and Safety (ACRES). He is a Founding Member of the Global Alliance of Publication Professionals (GAPP), a Past President of AMWA, and a Fellow of both AMWA and EMWA. Art served in a Senior Advisory capacity on the Budapest Working Group in developing the CORE Reference. He has a particular interest in bioethics in the context of clinical studies, is an advisor to an IRB, and serves on a number of task forces focusing on improving the drug development process while protecting the rights and safety of clinical study participants.

Douglas Fiebig

After 8 years in academic research (much of the time spent wading in rivers), Douglas was fortunate to chance upon a job advert that would launch his career in medical writing. It soon became clear to him that, in addition to keeping his feet dry, working as a medical writer was surely the most enjoyable way to earn a living using his scientific and linguistic skills. He has been involved in regulatory medical writing since 1996. Together with two partners, he took the plunge in 2002 and established Trilogy Writing & Consulting, a specialist medical writing company. Many years of writing pre- and post-submission documentation provide the inspiration for his EMWA workshops. Douglas served on the EMWA Professional Development Committee (EPDC) from 2009 - 2013.

EUROPEAN MEDICAL WRITERS ASSOCIATION

DDF11a Subject Narratives for Clinical Study Reports

Profile: This workshop is intended for medical writers who are familiar with the clinical development process but have no or limited experience in writing subject narratives for clinical study reports.

Objective: Participants will acquire knowledge of the requirements and criteria for writing subject narratives within the framework of relevant ICH guidelines. They will obtain an understanding of the narrative writing process, including sources of data, presentation of information, important functional groups contributing to the narratives, and techniques for narrative generation. This will enable the writer to prepare high-quality narratives and optimise narrative writing activities.

Content: The following topics will be discussed during the first part of the workshop:

- Relevant sections of the ICH guidelines, emphasising the purpose of narratives
- Definition of narrative criteria and categories
- Content, including sources of information and data, the role of clinical trial and pharmacovigilance databases, recycling of information from CIOMS forms
- The narrative writing process, including formats, templates, use of programmed data, coordination with other functional groups, quality control, tips for handling narratives in large studies

During the second part of the workshop participants will be divided into groups and asked to write a simple narrative based on tables and listings.

James Visanji

James holds a PhD in Medicine from the University of Manchester, Masters in Clinical Genetics from the University of Sheffield, Chartered Linguist status from the Chartered Institute of Linguists, and the European Medical Writers Association Nick Thompson Fellowship.
After postdoctoral work at Istituto Europeo di Oncologia, James started his medical writing career in 2006. Based in Frankfurt, he is currently Associate Director of Clinical Writing at Certara Insight, and was previously Medical Writing Manager at Trilogy Writing, and Deputy Director at Accovion (now Clinipace).
James focuses on clinical and regulatory documentation, in particular, submission dossiers and subsequent regulatory interactions. James has been training medical writers and physicians since 2012, and claims to get his biggest buzz from making the next generation of writers as effective as possible, as quickly as possible.

DDF12 The Clinical Study Protocol: Content and Structure

Profile: The workshop is intended for medical writers with little or no experience of writing clinical study protocols (CSPs), although basic knowledge of the clinical development process is expected.

Objective: The objective of this workshop is to introduce participants to the elements of the CSP. The emphasis will be on the formal content and structure of the CSP document; aspects of the process of CSP preparation, as well as indication-specific content, will only be marginally mentioned. On completion of the workshop, participants should feel more confident in accepting responsibility for the development of a CSP; in line with this, they should feel encouraged to work towards medical writing involvement in CSP preparation.

Content: The idea of this workshop is based on the following scenario: a sound and approved CSP outline is given to a medical writer who is charged with the preparation of the complete CSP document including all attachments. Assuming maximum freedom, what should a good CSP document look like? Which type of information should be included, and how should it be grouped? To this end, the workshop will include a discussion of the principles that should drive the selection of CSP content elements, followed by a proposed detailed structure of a CSP document.

Walther Seiler

After a classical education as a zoologist, **Walther Seiler** gained his PhD in neuroendocrinology at the University of Mainz, Germany. Throughout his academic career, he enjoyed interpreting and presenting data at least as much as generating them, so medical writing was a logical career step. After several years of medical writing in an international CRO, Walther moved to a global pharma company, overall gaining 25 years of medical writing experience. Clinical study protocols (CSPs) soon caught Walther's interest because they form the basis for many important downstream clinical documents. For many years, Walther has been involved in the development and maintenance of his company's CSP template

DDF13 Basic Concepts of Study Design in Clinical Development

Profile: This workshop is aimed at writers who wish to learn about the concepts underlying clinical development (e.g. the standard sections of a study protocol aimed at proving efficacy or the literature on clinical trials of efficacy). The workshop is suitable for those setting out to write regulatory documents as well as those who already have experience in medical communications or medical publishing who wish to understand the concepts underlying experimental study design.

Objective: To raise basic understanding of both study design and study conduct issues and the importance of these for valid and relevant experiments in trials intended as confirmatory studies of efficacy.

Content: This workshop focuses on the theoretical concepts underlying good design and not the process of either protocol or report generation, nor the wider content of these documents.

The following topics are covered:

- The design characteristics of a confirmatory study of efficacy
- The relationship between the study objective, the study hypotheses, the choice of endpoint and choice of control group
- Factors governing the identification of the study population
- The basis of sample size and its relationship with 'power'
- Robustness of data based on the example of the full analysis set (also known as ITT) and a per protocol analysis set
- Bias: blinding and randomising to treatment groups and identifying bias in data
- The relationship between statistical significance, clinical relevance and 'generalisability'

There will be classroom-format presentations as well as group exercises. The approach is intuitive, not statistical.

Rosemary Bischoff

Rosie has been in the pharmaceutical industry since 1974; most of that time as a clinical project leader for a pharmaceutical company in Berlin where she was responsible for the design, conduct and reporting of numerous studies. However, she began her career there writing manuscripts for publication in English and German and ended it as head of clinical operations for the business unit Therapeutics. In 1998 she started her own medical writing business, ClinWrite. She also served on the EMWA Professional Development Committee (EPDC) for many years.

Adam Jacobs

After getting bored of his first two careers (organic chemistry research and medical translating), Adam worked as a medical writer, first at a small contract research organisation and then at a large medical communications agency. He set up his own business in 1999, which was a lot of fun for a while but sadly didn't survive the recession and ceased trading in 2014. Adam was EMWA President in 2004–2005 and was co-author of EMWA's guidelines on the role of professional medical writers in publications. He finally got bored of medical writing as well, and now works as a statistician. However, he doubts he will ever get bored of coming to EMWA conferences.

EUROPEAN MEDICAL WRITERS ASSOCIATION

DDF17a Ethical Issues in Clinical Trials

Profile: This workshop is intended for medical writers (and others) who are interested in clinical trials and would like to know more about the evolution of ethical principles associated with human subject participation. Global ethical aspects that are taken into consideration for studies will be reviewed. In addition, case examples of situational clinical trial and medical ethics will be provided for interactive discussion.

Objective: To give an overview of the various ethical considerations associated with conducting clinical trials and associated policies and processes, including institutional oversight, pre-approval access, regulatory authority clearance, subject informed consent, investigatory conflict of interest, issues of fraud, and ensuring subject safety and well-being.

Content: This workshop will consist of a combination of presentations on relevant ethical issues, with respect to clinical trials, and group discussions on challenging ethical considerations of some "real-world" case studies. The presentations will focus on the importance of ethics in GCP, the informed consent process, and the challenges that may arise in developing countries. Practical experience will be shared with the participants.

Art Gertel

Art has a background in neurophysiology and behavioural medicine. As an independent consultant, he specialises in regulatory strategy, Data Safety Monitoring Board management, medical writing, and bioethics. Art has held senior posts at a number of companies including Schering-Plough/Merck, Hoffmann-LaRoche, TFS, and Quintiles, and headed departments responsible for medical writing, publications, project management, and regulatory affairs. He also served as a Senior Research Fellow with the Centre for Innovation in Regulatory Sciences (CIRS). Art has extensive teaching experience and has presented to professional organisations (e.g. EMWA, AMWA, DIA), and corporate and academic audiences, worldwide. He spent 2 years heading Clinical Operations for an eDC 'dot.com' company, and has been active in CDISC since its inception. He served as Chair of the Global Ethics and Regulatory Initiative (GERI) of the Alliance for Clinical Research Excellence and Safety (ACRES). He is a Founding Member of the Global Alliance of Publication Professionals (GAPP), a Past President of AMWA, and a Fellow of both AMWA and EMWA. Art served in a Senior Advisory capacity on the Budapest Working Group in developing the CORE Reference. He has a particular interest in bioethics in the context of clinical studies, is an advisor to an IRB, and serves on a number of task forces focusing on improving the drug development process while protecting the rights and safety of clinical study participants.

EUROPEAN MEDICAL WRITERS ASSOCIATION

DDF17b Ethical Issues in Health Care

Profile: This workshop is intended for medical writers (and others) who are interested in research and development of new medicines, and how decisions are made about how these are provided to patients. Global ethical aspects that are taken into consideration for studies will be reviewed. In addition, case examples of situational clinical research, healthcare, and medical ethics will be provided for interactive discussion.

Objective: To give an overview of the various ethical considerations associated with conducting clinical trials, and associated policies and processes, including institutional oversight, pre-approval access, regulatory authority clearance, subject informed consent, investigatory conflict of interest, issues of fraud, and ensuring subject safety and well-being.

Content: This workshop will consist of a combination of presentations on the evolution of ethical principles associated with human subject participation; relevant ethical issues, with respect to clinical research and development, clinical trials, societal healthcare decisions; and group discussions on challenging ethical considerations of some "real-world" case studies. The presentations will focus on the importance of ethics in GCP, human subject protections, and the dynamic tension between the individual and societal needs. Practical experience will be shared with the participants.

Art Gertel

Art has a background in neurophysiology and behavioural medicine. As an independent consultant, he specialises in regulatory strategy, Data Safety Monitoring Board management, medical writing, and bioethics. Art has held senior posts at a number of companies including Schering-Plough/Merck, Hoffmann-LaRoche, TFS, and Quintiles, and headed departments responsible for medical writing, publications, project management, and regulatory affairs. He also served as a Senior Research Fellow with the Centre for Innovation in Regulatory Sciences (CIRS). Art has extensive teaching experience and has presented to professional organisations (e.g. EMWA, AMWA, DIA), and corporate and academic audiences, worldwide. He spent 2 years heading Clinical Operations for an eDC 'dot.com' company, and has been active in CDISC since its inception. He served as Chair of the Global Ethics and Regulatory Initiative (GERI) of the Alliance for Clinical Research Excellence and Safety (ACRES). He is a Founding Member of the Global Alliance of Publication Professionals (GAPP), a Past President of AMWA, and a Fellow of both AMWA and EMWA. Art served in a Senior Advisory capacity on the Budapest Working Group in

developing the CORE Reference. He has a particular interest in bioethics in the context of clinical studies, is an advisor to an IRB, and serves on a number of task forces focusing on improving the drug development process while protecting the rights and safety of clinical study participants.

DDF18 Good SOP Practice: Processes and Authoring

Profile: Medical writers working in clinical research organisations or the pharmaceutical company environment, as either employees or as freelancers. The workshop will meet the needs of writers following, reviewing and revising existing Standard Operating Procedures (SOPs), or creating new SOPs. This is an ideal forum for writers whose organisations or clients have scope to improve their SOPs.

Objective:
• To view SOPs from several perspectives and use this valuable multi-dimensional view in SOP development
• To link process to writing and reviewing from the outset
• To discuss good (and poor) SOP practices in detail
• To put theory into practice using in-workshop exercises
• To place SOPs in the current context by considering their place and management in the electronic environment
• To understand how to create and maintain good SOPs or review existing SOPs

Content:

• What is an SOP?
• Why do we need SOPs?
• Using, reviewing and creating SOPs: A multi-dimensional perspective
• SOP components
• Planning the SOP
• Language and authoring tips
• SOPs in an electronic age

Sam Hamilton

Sam Hamilton is a postdoctoral virologist, with 28 years in clinical and regulatory medical writing and leadership roles in the pharmaceutical industry. Sam has a special interest in public disclosure of clinical-regulatory documents as Chair of the EMWA-AMWA group who delivered the open-access www.core-reference.org in May 2016. Sam is long-time supporter of EMWA serving in various roles over 15 years, notably as Freelance Advocate; Editorial Board member for Medical Writing (MEW); Workshop Leader; Expert Seminar Series (ESS) Chair; and Vice President and President. Sam was elected an EMWA Nick Thompson Fellow in 2018 for her services

to the Association. Sam is currently MEW Section Editor for the "Regulatory Public Disclosure" Section, and Chair of The CORE Reference Project.

Tracy Farrow

Tracy is currently Executive Director, Medical Writing and Healthcare Communications for Evidera where she provides senior-direction and decision making to a global team of medical writing professionals who deliver document development services across the spectrum of peri- and post-approval studies, and strategic writing services including study documents, manuscripts, publication planning, and posters. Tracy has more than 25 years of Biomedical Science experience. Prior to joining Evidera, Tracy was employed by Evidera's parent company PPD. Her roles included senior director, director, and associate director with operational responsibilities over clinical medical writing teams. Prior to joining the medical writing group at PPD, Tracy served as a manager of medical writing services for ClinTec International Ltd.; and Pfizer as Medical Writing Therapeutic Area Lead, and Quality Manager for Data Management where she was responsible for data privacy training, audit management, SOP and best practice development. She lectured in Intermediate Laboratory Data Management for the Association for Clinical Data Management for a number of years as part of their professional development program. She attained her 2.1 (Hons) GI Biol in Biochemistry in 1993 after gaining two Higher National Certificates in Haematology and Chemistry. Tracy is the Co-Chair of the EMWA Regulatory Public Disclosure Special Interest Group and is an active contributor to EMWA. From May 2014, Tracy has been a member of the EMWA-AMWA Budapest Working Group Oversight Review Team, with special responsibility for the area of transparency and public disclosure in relation to clinical-regulatory documents.

DDF20 GCP Training for Medical Writers

Profile: This workshop is intended for writers with little Good Clinical Practice (GCP) experience whose work involves clinical trial documents e.g. informed consent forms, protocols and reports.

Objective: An understanding of the principles of GCP and how they can be applied in the writing and reviewing of clinical research documents e.g. informed consent forms, clinical study protocols, and regulatory documents e.g. clinical study reports, clinical overviews and summaries.

Content: The first part of the workshop will provide an overview of the principles of GCP, including the Declaration of Helsinki, the ICH E6 GCP Guideline and the Clinical Trial Directive 2001/20/EC and its amendments. The second part of the workshop will focus on how to ensure that documents are GCP-compliant, and the cross-checks that can be made, particularly when writing clinical study reports.

Gillian Pritchard

Gillian Pritchard (Director, Sylexis Limited, UK) is a regulatory medical writer specialising in writing clinical evaluation reports and literature reviews for medical devices. She has worked on medical devices for orthopaedic, cardiology, ophthalmology, gynaecology, wound closure, diabetes and weight loss indications. Gillian trained as a physician and has many years' experience as a research physician in academia and phase I-II contract research; as a clinical project manager of phase III trials with Pfizer GRD; and also with a pharmaceutical and medical devices consultancy. In 2006 Gillian established Sylexis Ltd. to provide regulatory writing services for pharmaceutical and medical device clients. Gillian gives workshops on literature reviews, clinical evaluation reports, drug safety (adverse events and laboratory safety), ICH-GCP and on moving from pharma to medical device writing. She was EMWA Treasurer from 2009 to 2013 and is a member of the Medical Device Special Interest Group (MD SIG).

DDF20a GCP Training for Medical Writers

Profile: This workshop is intended for writers with little Good Clinical Practice (GCP) experience whose work involves clinical trial documents e.g. informed consent forms, protocols and reports.

Objective: An understanding of the principles of GCP and how they can be applied in the writing and reviewing of clinical research documents e.g. informed consent forms, clinical study protocols, and regulatory documents e.g. clinical study reports, clinical overviews and summaries.

Content: The first part of the workshop will provide an overview of the principles of GCP, including the Declaration of Helsinki, the ICH E6 GCP Guideline, the EU Clinical Trial Regulation 536/2014 and ISO 14155:2020. The second part of the workshop will focus on how to ensure that documents are GCP-compliant, and the cross-checks that can be made, particularly when writing clinical study reports.

Raquel Billiones

Raquel Billiones has a PhD in Biology and more than 25 years combined experience in scientific and clinical research. She has been a medical writer for >15 years, with core competencies in writing clinical trial and regulatory documents for pharmaceuticals and medical devices. Her experience also includes transparency, disclosure and patient data protection in clinical trial data reporting. Over the years, she took on a wide range of industry positions, as freelancer, employed regulatory writer, and as head of medical writing departments in the CRO and big pharma settings. Raquel is an active member of EMWA, serving in various roles, including

•Medical Writing editorial board member since 2010, currently Editor-in-Chief
•Education Committee member and workshop leader
•Co-founder of the SIGs on Medical Devices and on Sustainability.

Gillian Pritchard

Gillian Pritchard (Director, Sylexis Limited, UK) is a regulatory medical writer specialising in writing clinical evaluation reports and literature reviews for medical devices. She has worked on medical devices for orthopaedic, cardiology, ophthalmology, gynaecology, wound closure, diabetes and weight loss indications. Gillian trained as a physician and has many years' experience as a research physician in academia and phase I-II contract research; as a clinical project manager of phase III trials with Pfizer GRD; and also with a pharmaceutical and medical devices consultancy. In 2006 Gillian established Sylexis Ltd. to provide regulatory writing services for pharmaceutical and medical device clients. Gillian gives workshops on literature reviews, clinical evaluation reports, drug safety (adverse events and laboratory safety), ICH-GCP and on moving from pharma to medical device writing. She was EMWA Treasurer from 2009 to 2013 and is a member of the Medical Device Special Interest Group (MD SIG).

DDF22 Drug Safety for Medical Writers Part 1: Adverse Events and Concomitant Medications

Profile: This workshop is intended for people who are new to medical writing and who are involved in writing the safety sections of clinical study reports or related safety summaries.

Objective: This workshop is designed to give medical writers insight into the processes by which adverse event and concomitant medication data are generated and recorded during clinical trials and the subsequent handling of the data. On completion of the workshop package, participants should be confident in their approach to writing the adverse event and concomitant medication sections of documents relating to clinical trials.

Content: The role of the medical writer in preparing summaries of safety data is to take a large amount of information and to present the most important points in a useful and understandable format. The challenge for the writer is to identify what is important and to answer the readers' questions before they have been asked. The collection of clinical safety data on a drug begins at the clinical trial level. All safety summaries are built upon this starting point. The aim of the workshop is to bring the data to life so that the writer can present safety data that is interesting to the reader.

EUROPEAN MEDICAL WRITERS ASSOCIATION

Wendy Kingdom

Wendy has more than 30 years' experience of clinical research and medical writing in the pharmaceutical industry. She started her career as a clinical research associate; writing protocols, preparing related study documents, managing studies, and writing clinical study reports. She has been working successfully as a freelance medical writer since 2002 and specialises in clinical and regulatory documents. She has provided commercial and academic training on medical writing. Wendy was EMWA Education Officer 2003–2005, served on the EMWA Professional Development Committee (EPDC) for 5 years, and was Treasurer of EMWA from 2005–2009.

Gillian Pritchard

Gillian Pritchard (Director, Sylexis Limited, UK) is a regulatory medical writer specialising in writing clinical evaluation reports and literature reviews for medical devices. She has worked on medical devices for orthopaedic, cardiology, ophthalmology, gynaecology, wound closure, diabetes and weight loss indications. Gillian trained as a physician and has many years' experience as a research physician in academia and phase I-II contract research; as a clinical project manager of phase III trials with Pfizer GRD; and also with a pharmaceutical and medical devices consultancy. In 2006 Gillian established Sylexis Ltd. to provide regulatory writing services for pharmaceutical and medical device clients. Gillian gives workshops on literature reviews, clinical evaluation reports, drug safety (adverse events and laboratory safety), ICH-GCP and on moving from pharma to medical device writing. She was EMWA Treasurer from 2009 to 2013 and is a member of the Medical Device Special Interest Group (MD SIG).

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Gillian Pritchard

Gillian Pritchard (Director, Sylexis Limited, UK) is a regulatory medical writer specialising in writing clinical evaluation reports and literature reviews for medical devices. She has worked on medical devices for orthopaedic, cardiology, ophthalmology, gynaecology, wound closure, diabetes and weight loss indications. Gillian trained as a physician and has many years' experience as a research physician in academia and phase I-II contract research; as a clinical project manager of phase III trials with Pfizer GRD; and also with a pharmaceutical and medical devices consultancy. In 2006 Gillian established Sylexis Ltd. to provide regulatory writing services for pharmaceutical and medical device clients. Gillian gives workshops on literature reviews, clinical evaluation reports, drug safety (adverse events and laboratory safety), ICH-GCP and on moving from pharma to medical device writing. She was EMWA Treasurer from 2009 to 2013 and is a member of the Medical Device Special Interest Group (MD SIG).

DDF22b Drug Safety for Medical Writers Part 1: Adverse Events and Concomitant Medications

Profile: This workshop is intended for people who are new to medical writing and who are involved in writing the safety sections of clinical study reports or related safety summaries.

Objective: This workshop is designed to give medical writers insight into the processes by which adverse event and concomitant medication data are generated and recorded during clinical trials and the subsequent handling of the data. On completion of the workshop package, participants should be confident in their approach to writing the adverse event and concomitant medication sections of documents relating to clinical trials.

Content: The role of the medical writer in preparing summaries of safety data is to take a large amount of information and to present the most important points in a useful and understandable format. The challenge for the writer is to identify what is important and to answer the readers' questions before they have been asked. The collection of clinical safety data on a drug begins at the clinical trial level. All safety

summaries are built upon this starting point. Coding of adverse event and concomitant medication data will be described and discussed because of its importance in safety data reporting. The aim of the workshop is to bring the data to life so that the writer can present safety data that is meaningful and interesting to the reader.

Wendy Kingdom

Wendy has more than 30 years' experience of clinical research and medical writing in the pharmaceutical industry. She started her career as a clinical research associate; writing protocols, preparing related study documents, managing studies, and writing clinical study reports. She has been working successfully as a freelance medical writer since 2002 and specialises in clinical and regulatory documents. She has provided commercial and academic training on medical writing. Wendy was EMWA Education Officer 2003–2005, served on the EMWA Professional Development Committee (EPDC) for 5 years, and was Treasurer of EMWA from 2005–2009.

DDF23 Drug Safety for Medical Writers Part 2: Laboratory Data

Profile: This workshop is intended for medical writers who are new to writing the safety sections of clinical study reports or related safety summaries.

Objective: This workshop is designed to give medical writers insight into the processes by which laboratory data, vital signs and ECG data are generated and recorded during clinical trials and the subsequent handling of these data. On completion of the workshop package, participants should be confident in their approach to writing the laboratory and other safety data sections of documents relating to clinical trials, particularly clinical study reports.

Content: The role of the medical writer in preparing summaries of safety data are to take a large amount of information and to present the most important points in a useful and understandable format. The challenge for the writer is to identify what is important and to answer the readers' questions before they have been asked. The collection of laboratory, vital sign and ECG data on a drug begins at the clinical trial level. All safety summaries are built upon this starting point. The aim of the workshop is to bring the data to life so that the writer can present safety data that are interesting to the reader.

Wendy Kingdom

Wendy has more than 30 years' experience of clinical research and medical writing in the pharmaceutical industry. She started her career as a clinical research associate; writing protocols, preparing related study documents, managing studies,

and writing clinical study reports. She has been working successfully as a freelance medical writer since 2002 and specialises in clinical and regulatory documents. She has provided commercial and academic training on medical writing. Wendy was EMWA Education Officer 2003–2005, served on the EMWA Professional Development Committee (EPDC) for 5 years, and was Treasurer of EMWA from 2005–2009.

Gillian Pritchard

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DDF23a Drug Safety for Medical Writers Part 2: Laboratory Data

Profile: This workshop is intended for medical writers who are new to writing the safety sections of clinical study reports or related safety summaries.

Objective: This workshop is designed to give medical writers insight into the processes by which laboratory data, vital signs and ECG data are generated and recorded during clinical trials and the subsequent handling of these data. On completion of the workshop package, participants should be confident in their approach to writing the laboratory and other safety data sections of documents relating to clinical trials, particularly clinical study reports.

Content: The role of the medical writer in preparing summaries of safety data are to take a large amount of information and to present the most important points in a useful and understandable format. The challenge for the writer is to identify what is important and to answer the readers' questions before they have been asked. The collection of laboratory, vital sign and ECG data on a drug begins at the clinical trial level. All safety summaries are built upon this starting point. The aim of the workshop is to bring the data to life so that the writer can present safety data that are interesting to the reader.

EUROPEAN MEDICAL WRITERS ASSOCIATION

Gillian Pritchard

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DDF27 A Beginner's Guide to Key Clinical Documents in Drug Development

Profile: This workshop is designed for people who are new to medical writing in general, and those who are new to regulatory writing.

Objective: For new medical writers, the number of documents prepared during the course of drug development can be overwhelming. The objective of this workshop is to give new medical writers an overview of some of the key clinical documents that they may be asked to prepare. The workshop will explain the purpose of the different documents, how they all fit together, and how this affects the way that each document is written.

Content:
The role of each of the documents listed below in the drug development process will be described in the order they are developed:

- Investigator's brochure (IB)
- Investigational medicinal product dossier (IMPD)
- Clinical study synopsis
- Clinical study protocol (statistical analysis plans, case report forms, patient information and informed consent forms)
- Clinical study report (CSR)
- Paediatric investigation plan (PIP)
- Common technical document (CTD) clinical overview (Section 2.5) and clinical summary (Section 2.7)
- Summary of product characteristics (SPC)
- Patient information leaflets (PILs)

- Risk management plan (RMP)
- Periodic safety update report (PSURs) and drug safety update reports (DSURs)

For each type of document, the following will be summarised:

- The purpose of the document: who will use it and how
- How the purpose affects the writing
- Who is involved in producing it and the role of the medical writer in its preparation
- Where the information in each document comes from
- How it fits with the other documents
- Similarities and differences to other documents

Antonia Pickup

Antonia is a Senior Medical Writer working for Scinopsis in the south of France. Having completed a degree in biology, Antonia worked as a project manager and researcher within the UK National Health Service, after which she became a professional grant application writer. Medical writing provided the opportunity to combine skills learnt in both of these environments. Antonia now has seven years' experience of writing a wide range of regulatory and medical communications documents for clients ranging from some of the largest pharmaceutical companies to charities and independent researchers.

DDF29 Protocol Amendments

Profile: The workshop is intended for medical writers with little or no experience of writing protocol amendments, although basic knowledge of the clinical development process is expected. Moreover, it is recommended that participants had already taken Workshop DDF12 (Content and structure of clinical study protocols; version 2014) although this is not a must.
Note: Until 2013 inclusive, the topic of protocol amendments had been part of Workshop DDF12. Therefore, anyone having taken DDF12 in 2013 or earlier is unlikely to fully benefit from Workshop DDF29.

Objective: On completion of the workshop, participants should feel more confident in accepting medical-writing responsibility for the development of a CSP amendment; they should also feel encouraged to work towards thorough medical writing involvement in the preparation of CSP amendments.

Content: The workshop will give an overview of what protocol amendments are and how to write them. Content and form of different amendment options (stand-alone amendment versus amended "integrated" CSP)he will be introduced. Key aspects of the process of amendment development will also be covered (Under which circumstances is a CSP amendment needed? How to develop the CSP amendment).

Walther Seiler

After a classical education as a zoologist, **Walther Seiler** gained his PhD in neuroendocrinology at the University of Mainz, Germany. Throughout his academic career, he enjoyed interpreting and presenting data at least as much as generating them, so medical writing was a logical career step. After several years of medical writing in an international CRO, Walther moved to a global pharma company, overall gaining 25 years of medical writing experience. Clinical study protocols (CSPs) soon caught Walther's interest because they form the basis for many important downstream clinical documents. For many years, Walther has been involved in the development and maintenance of his company's CSP template

DDF2a The Investigator's Brochure

Profile: Medical writers with at least 1 year of experience in the pharmaceutical industry.

Objective:

- Learn what the ICH and regulatory guidelines say about the Investigator's Brochure (IB)
- Learn useful tools and advice for the actual writing, compiling, and managing of an IB project
- Experience the dynamics of team writing and editing as it pertains to an IB

Content: The IB is definitely the poor cousin among regulatory documents in the pharmaceutical industry. It rarely gets the resources and time required to do it properly. It can also be the bane of the medical writer's life, as 'quick update' projects often turn out to involve excruciating re-formatting and consistency checks. In the first part of the course, participants will learn the 'theory' of IB writing, i.e. what the ICH and regulatory guidelines say, as well as tools to be used in successful IB writing gleaned from the extensive experience of the workshop leader. In the second part of the course, participants will work in teams to prepare a mini-IB based on actual data and compare their results to those of the other teams.

Douglas Fiebig

After 8 years in academic research (much of the time spent wading in rivers), Douglas was fortunate to chance upon a job advert that would launch his career in medical writing. It soon became clear to him that, in addition to keeping his feet dry, working as a medical writer was surely the most enjoyable way to earn a living using his scientific and linguistic skills. He has been involved in regulatory medical writing since 1996. Together with two partners, he took the plunge in 2002 and established Trilogy Writing & Consulting, a specialist medical writing company. Many years of writing pre- and post-submission documentation provide the inspiration for his

EMWA workshops. Douglas served on the EMWA Professional Development Committee (EPDC) from 2009 - 2013.

DDF30 - Writing Risk Management Plans

Profile: Aimed at medical writers with little or no experience of writing risk management plans (RMPs), but with a basic knowledge of the overall drug development process and some experience in assessing and presenting non-clinical and clinical data on drug safety and risks. Ideally, participants with no knowledge in pharmacovigilance should attend the foundation workshop on pharmacovigilance writing (DDF32) prior to register to this workshop. Writers with more experience of RMPs should consider EMWA's advanced workshop on the topic, DDA20.

Objective: To learn about the structure, content and requirements of RMPs according to the 'EU Pharma Package', which came into force in July 2012. At the end of the workshop, participants will be able to understand the focus of RMPs, identify the right content and language for each section, and collecting informations to prepare an RMP.

Content: This workshop will provide an overview of the preparation of RMPs according to Good Pharmacovigilance Practice (GVP). Participants will learn where to find relevant guidance and which source documents should be used while preparing RMPs within multidisciplinary teams. The most relevant drug safety concepts for RMPs (e.g. important identified and potential risk) will be explained, then the structure and content of the RMP will be presented and selected issues will be explored in exercises. Emphasis will be given to the focus, content, and data presentation of different RMP sections.

Tiziana von Bruchhausen

Principal Global Pharmacovigilance Writer – Boehringer Ingelheim Pharma
Tiziana has been specialising in pharmacovigilance writing since 2008 and has gained extensive hands-on experience with pharmacovigilance documents and health authorities' assessments. She has developed broad expertise with the implementation of the GVP guideline related to RMPs and PSURs, and with the evolving concept of safety concerns. In her current position at Boehringer Ingelheim, she is responsible for the coordination and preparation of lifecycle pharmacovigilance documents with a focus on DSURs, RMPs, and PSURs; in addition, she is involved in pre- and post-submission activities related to the global strategic planning and health authorities' assessment reports.
Tiziana provides trainings on pharmacovigilance writing for professional education institutions Europe-wide, including EMWA. She is an active volunteer for EMWA, where she was Vice President/President in 2017-2019; she has been chairing the

Pharmacovigilance Special Interest Group (SIG) since 2017, and since May 2021 she has been on the Committee of the Communicating with the Public SIG.

DDF32 Introduction to Pharmacovigilance Writing

Profile: Writers who want to better understand the different types of pharmacovigilance (PV) documents, when and why they are needed and how they interact with each other. It is recommended that this workshop is completed before attending the advanced workshops for writing Risk Management Plans (RMP), Development Safety Update Reports (DSUR), and Periodic Benefit-Risk Evaluation Reports (PBRER).

Objective: After completing this workshop, participants will have basic understanding of the different PV documents required by the regulatory authorities both prior to marketing and post-marketing. They will understand the purpose of the documents, when they are required, how they interact and overlap with each other and what guidance is available to help in preparation of them. In addition, they will be introduced to the difference of the safety data collected in clinical trials and post-marketing.

Content: In depth document content and format is covered in other document-specific workshops. This workshop will provide a basic overview of RMP, DSUR and PBRER, and explain the standard terms and definitions routinely used in PV documents. It will discuss overlaps and links between these documents, available guidance, when and why the documents are needed, who uses them, and what the roles medical writers in clinical development and PV have in developing the documents.

Tiziana von Bruchhausen

Principal Global Pharmacovigilance Writer – Boehringer Ingelheim Pharma

Tiziana has been specialising in pharmacovigilance writing since 2008 and has gained extensive hands-on experience with pharmacovigilance documents and health authorities' assessments. She has developed broad expertise with the implementation of the GVP guideline related to RMPs and PSURs, and with the evolving concept of safety concerns. In her current position at Boehringer Ingelheim, she is responsible for the coordination and preparation of lifecycle pharmacovigilance documents with a focus on DSURs, RMPs, and PSURs; in addition, she is involved in pre- and post-submission activities related to the global strategic planning and health authorities' assessment reports.

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Pharmacovigilance Special Interest Group (SIG) since 2017, and since May 2021 she has been on the Committee of the Communicating with the Public SIG.

Sven Schirp

Sven Schirp started his medical writing career in 1997. To date, he has covered a wide range of medical writing services, from biomedical publications and pharmacovigilance documents to global marketing applications. He is currently Global Head of Patient Safety Writing at Boehringer Ingelheim and has developed and led multiple workshops for DIA and EMWA.

DDF32a Introduction to Pharmacovigilance Writing

Profile: Writers who want to better understand the different types of pharmacovigilance (PV) documents, when and why they are needed and how they interact with each other. It is recommended that this workshop is completed before attending the advanced workshops for writing Risk Management Plans (RMP), Development Safety Update Reports (DSUR), and Periodic Benefit-Risk Evaluation Reports (PBRER).

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EUROPEAN MEDICAL WRITERS ASSOCIATION

Stefanie Rechtsteiner

Stefanie has been working in the pharmaceutical industry for many years, starting in biotech, moving on to marketing/sales, until she specialised in safety writing from 2011 onwards. She has extensive hands-on experience on DSUR, RMP, AddCO, and PBRER writing and currently works as a principal pharmacovigilance writer at Boehringer Ingelheim. Stefanie joined EMWA in 2011 and has offered various workshops on safety writing at EMWA over the past years.

DDF32b Introduction to Pharmacovigilance Writing

Profile: Writers who want to better understand the different types of pharmacovigilance (PV) documents, when and why they are needed and how they interact with each other. It is recommended that this workshop is completed before attending the advanced workshops for writing Risk Management Plans (RMP), Development Safety Update Reports (DSUR), and Periodic Benefit-Risk Evaluation Reports (PBRER).

Objective: After completing this workshop, participants will have basic understanding of the different PV documents required by the regulatory authorities both prior to marketing and post-marketing. They will understand the purpose of the documents, when they are required, how they interact and overlap with each other and what guidance is available to help in preparation of them. In addition, they will be introduced to the difference of the safety data collected in clinical trials and post-marketing.

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Tiziana von Bruchhausen

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Tiziana provides trainings on pharmacovigilance writing for professional education institutions Europe-wide, including EMWA. She is an active volunteer for EMWA, where she was Vice President/President in 2017-2019; she has been chairing the Pharmacovigilance Special Interest Group (SIG) since 2017, and since May 2021 she has been on the Committee of the Communicating with the Public SIG.

DDF33+34a Clinical Study Reports - Mastering the Essential Skills (Double workshop)

Profile: This course is intended for medical writers with no or little experience of writing clinical study reports (CSRs).

Objective: The objective of this workshop is to equip you with the essential skills required for the management and preparation of high quality CSRs. This includes in-depth sessions on both the writing of CSRs as well as their project management. The workshop will include group exercises and discussions so that participants can develop new skills attained and learn from each other's experiences.

Content: This double workshop brings together different aspects of knowledge and medical writing skills required (covered in depth in other workshops) for the production of CSRs.

The course will cover:

- CSR project preparation and timelines
- Writing a CSR according to International Conference on Harmonisation (ICH) E3 guidelines and CORE reference
- Writing the methods sections: brief overview and advice
- Interpreting data, describing results: demography and baseline characteristics
- Interpreting data, describing results: efficacy; using the statistical report
- Interpreting data, describing results: safety and safety narratives
- Different types of CSRs: abbreviated CSR, full CSR, post-marketing reports, medical device reports
- CSR review and quality control
- Appendices: an overview

Sarah Tilly

Sarah values the people with whom she writes in the same way she values the patients about whom she writes, and the customers for whom she writes. She believes that everyone has their own, unique contribution to give to our industry. For this reason, Sarah has been involved in mentoring new medical writers since an early stage of her career. In parallel with her largely regulatory writing experience, she has managed and mentored several teams of writers and has been involved in setting up and coordinating training systems. Sarah has been medical writing since 2006 in clinical research organisations and medical writing consultancies. She set up

Azur Health Science in 2017 as Medical Writer and Director. She holds a first degree in Biology and a PGCert in International HTA, Pricing and Reimbursement.

Gaele Ducher

Gaele is a principal medical writer at Scinopsis. She worked in academic research for 10 years, in France, the UK, Australia and the US, with a specific interest in rheumatology, paediatrics, medical imaging and sport sciences. Gaele has a doctoral degree in physiology and published approximately 30 scientific articles during her research career. She has been a medical writer since 2011 and is experienced at writing a wide range of regulatory documents and medical communications covering various therapeutic areas.

DDF33 + 34b Clinical Study Reports - Mastering the Essential Skills (Double Workshop)

Profile: This course is intended for medical writers with no or little experience of writing clinical study reports (CSRs).

Objective: The objective of this workshop is to equip you with the essential skills required for the management and preparation of high quality CSRs. This includes in-depth sessions on both the writing of CSRs as well as their project management. The workshop will include group exercises and discussions so that participants can develop new skills attained and learn from each other's experiences.

Content: This double workshop brings together different aspects of knowledge and medical writing skills required (covered in depth in other workshops) for the production of CSRs.

The course will cover:

- CSR project preparation and timelines
- Writing a CSR according to International Conference on Harmonisation (ICH) E3 guidelines and CORE reference
- Writing the methods sections: brief overview and advice
- Interpreting data, describing results: demography and baseline characteristics
- Interpreting data, describing results: efficacy; using the statistical report
- Interpreting data, describing results: safety and safety narratives
- Different types of CSRs: abbreviated CSR, full CSR, post-marketing reports, medical device reports
- CSR review and quality control
- Appendices: an overview

Gaele Ducher

Gaele is a principal medical writer at Scinopsis. She worked in academic research for 10 years, in France, the UK, Australia and the US, with a specific interest in rheumatology, paediatrics, medical imaging and sport sciences. Gaele has a doctoral

degree in physiology and published approximately 30 scientific articles during her research career. She has been a medical writer since 2011 and is experienced at writing a wide range of regulatory documents and medical communications covering various therapeutic areas.

Monica Milani

Monica has been a medical writer since 2011. She began her career in a busy medical writing company, moved to the pharmaceutical industry, and then transitioned into freelancing. She has experience in a wide range of regulatory and medical communication documents covering various therapeutic areas. Prior to medical writing, she worked in academia and authored numerous articles in the immunology and oncology fields. Monica holds degrees in biological sciences, biotechnology, and scientific/technical communication.

DDF33 + 34c Clinical Study Reports - Mastering the Essential Skills (Double Workshop in 2 parts)

Profile: This course is intended for medical writers with no or little experience of writing clinical study reports (CSRs).

Objective: The objective of this workshop is to equip you with the essential skills required for the management and preparation of high-quality CSRs. This includes in-depth sessions on both the writing of CSRs as well as their project management. The workshop will include group exercises and discussions so that participants can develop new skills attained and learn from each other's experiences.

Content: This double workshop brings together different aspects of knowledge and medical writing skills required (covered in depth in other workshops) for the production of CSRs.

The course will cover:

- CSR project preparation and timelines
- Current guidelines (International Council for Harmonisation [ICH] E3 guidance documents and CORE reference)
- Writing a CSR according to ICH E3
- Writing the methods sections: brief overview and advice
- Interpreting data, describing results: demography and baseline characteristics
- Interpreting data, describing results: efficacy; using the statistical report
- Interpreting data, describing results: safety and safety narratives
- Different types of CSRs: abbreviated CSR, full CSR, post-marketing reports, medical device reports
- CSR review and quality control

- Appendices: an overview

Monica Milani

Monica has been a medical writer since 2011. She began her career in a busy medical writing company, moved to the pharmaceutical industry, and then transitioned into freelancing. She has experience in a wide range of regulatory and medical communication documents covering various therapeutic areas. Prior to medical writing, she worked in academia and authored numerous articles in the immunology and oncology fields. Monica holds degrees in biological sciences, biotechnology, and scientific/technical communication.

Sarah Hopwood

Sarah is Chief Operating Officer & Director of Medical Writing at Scinopsis, a consultancy based in France and the UK. Sarah began her medical writing career in 2006, initially working in a busy international medical communications agency before joining the Scinopsis team in 2009. Prior to medical writing, she worked as a post-doctoral research scientist and authored numerous scientific publications in the field of neuroscience. Sarah is very experienced at writing a wide range of regulatory documents and medical communications covering many different therapeutic areas. She has been an active member of EMWA since 2007.

DDF 33+34d Clinical Study Reports - Mastering the Essential Skills (Double Workshop in 2 parts)

Profile: This course is intended for medical writers with no or little experience of writing clinical study reports (CSRs).

Objective: The objective of this workshop is to equip you with the essential skills required for the management and preparation of high-quality CSRs. This includes in-depth sessions on both the writing of CSRs as well as their project management. The workshop will include group exercises and discussions so that participants can develop new skills attained and learn from each other's experiences.

Content: This double workshop brings together different aspects of knowledge and medical writing skills required (covered in depth in other workshops) for the production of CSRs.

The course will cover:

- CSR project preparation and timelines
- Current guidelines (International Council for Harmonisation [ICH] E3 guidance documents and CORE reference)
- Writing a CSR according to ICH E3
- Writing the methods sections: brief overview and advice
- Interpreting data, describing results: demography and baseline characteristics

- Interpreting data, describing results: efficacy; using the statistical report
- Interpreting data, describing results: safety and safety narratives
- Different types of CSRs: abbreviated CSR, full CSR, post-marketing reports, medical device reports
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Sarah Hopwood

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Gaële Ducher

Gaele is a principal medical writer at Scinopsis. She worked in academic research for 10 years, in France, the UK, Australia and the US, with a specific interest in rheumatology, paediatrics, medical imaging and sport sciences. Gaele has a doctoral degree in physiology and published approximately 30 scientific articles during her research career. She has been a medical writer since 2011 and is experienced at writing a wide range of regulatory documents and medical communications covering various therapeutic areas.

DDF35 Introduction to Writing about Efficacy

Profile: This workshop is aimed at medical writers with little or no experience of writing about efficacy in clinical and regulatory documents. Basic knowledge of the clinical development process is expected.

Objective: The workshop aims to give participants a basic understanding of the general principles by which efficacy is evaluated in clinical trials. Participants will gain a broad awareness of the different kinds of efficacy endpoints and statistical analyses they are likely to encounter. The focus is not on detailed statistical theory, but on practical approaches to understanding efficacy analyses and reporting their results in a clinical study report, regardless of clinical indication. The workshop includes exercises designed to give participants hands-on practice at using statistical analysis plans to understand and describe efficacy analyses, and at interpreting data tables for efficacy. After completing the workshop, participants should be better equipped to write the efficacy sections of clinical documents.

Content: The workshop will cover: Introduction to efficacy • How is efficacy evaluated? • Estimating treatment effects • Hypotheses and statistical tests • Using statistical analysis plans • Understanding statistical output for efficacy • Efficacy in clinical study reports

Helen Bridge

Helen is a biologist and linguist who has always enjoyed both writing and interpreting data. After leaving her previous career as a university teacher and researcher in German literature, she completed a degree in life sciences with statistics, and became a medical writer in 2012. She worked in a CRO for 6 years before moving to AstraZeneca in March 2018. She has written a wide range of regulatory documents, with a particular focus on CTD clinical summaries and overviews, study reports, and protocols. She has recently completed an MSc in medical statistics.

DDF36 An Introduction to Clinical Trial Disclosure – the Regulatory Requirements, Industry Commitments, and Protection of Data Privacy and Company Confidential Information

Profile: This basic workshop is intended for participants directly or indirectly involved in the planning, analysis and/or reporting of clinical trials, or in the design of clinical development programs, or those with little or no background in this area who are interested in learning the basics. Previous experience or background knowledge of clinical trial disclosure is not required. This workshop will benefit newcomers to the topic, but also those simply wishing to update their knowledge of this topic.

Objective: Attending this workshop will help participants to understand the regulatory requirements (e.g., EMA Policies 043 and 070, the EU Clinical Trials Regulation [EU CTR], and national Freedom of Information laws) and industry commitments for clinical trial disclosure, understand how patients and investigational sites may benefit from this disclosure, be introduced to the new documents required due to the disclosure (EMA Policy 070 anonymization report, protocol lay synopsis, lay summaries, etc.), be aware of the challenges created by clinical trial disclosure for when drafting clinical documents (e.g., protocols, clinical study reports), understand what is company confidential information, personal protected information, and data privacy, and understand how data privacy and confidential information is protected (e.g., using anonymization or redaction).
Attending this basic workshop before attending one of the specialist workshops will enable participants to gain the most benefit from the advanced workshops.

Content: This will be an interactive workshop combining classical presentations with quizzes and exercises to introduce the topic. The aspects of clinical trial disclosure most relevant for medical writers, including potential new deliverables and challenges during protocol and CSR writing, will be highlighted. This workshop will enable attendees to embark upon workshops covering specialized topics such as the drafting of lay summaries, trial registration and results reporting in EudraCT/CTIS/clinicaltrials.gov, and the protection of protected personal data and commercially confidential data.

Christopher Marshallsay

Christopher Marshallsay is Head of Scientific/Medical Writing & Trial Transparency at BioNTech SE (Mainz, Germany). Christopher is a PhD biochemist with over 25 years of experience in various roles in clinical development - including pharmacokinetics, medical writing, clinical trial disclosure, and as department/function head - whilst located in Aachen, Frankfurt, Mainz, and Paris. He has previously worked at Ciba-Geigy, Aventis, Sanofi, and Grünenthal. He currently manages a group of teams providing integrated scientific, regulatory, and publication writing services for research, non-clinical, and clinical teams. His team also provides trial transparency services (clinical study registration/results posting, Policy 0043/70 requests, freedom of information requests, voluntary disclosure requests, and protection of company confidential information and personal protected information), and publication management and submission services. As a process nerd, Christopher is a key driver for process optimization and standardization at BioNTech. Christopher is also an experienced lecturer and workshop leader. He is a Committee Member of the Regulatory Public Disclosure Special Interest Group.

Tracy Farrow

Tracy is currently Executive Director, Medical Writing and Healthcare Communications for Evidera where she provides senior-direction and decision making to a global team of medical writing professionals who deliver document development services across the spectrum of peri- and post-approval studies, and strategic writing services including study documents, manuscripts, publication planning, and posters. Tracy has more than 25 years of Biomedical Science experience. Prior to joining Evidera, Tracy was employed by Evidera's parent company PPD. Her roles included senior director, director, and associate director with operational responsibilities over clinical medical writing teams. Prior to joining the medical writing group at PPD, Tracy served as a manager of medical writing services for ClinTec International Ltd.; and Pfizer as Medical Writing Therapeutic Area Lead, and Quality Manager for Data Management where she was responsible for data privacy training, audit management, SOP and best practice development. She lectured in Intermediate Laboratory Data Management for the Association for Clinical Data Management for a number of years as part of their professional development program. She attained her 2.1 (Hons) GI Biol in Biochemistry in 1993

after gaining two Higher National Certificates in Haematology and Chemistry. Tracy is the Co-Chair of the EMWA Regulatory Public Disclosure Special Interest Group and is an active contributor to EMWA. From May 2014, Tracy has been a member of the EMWA-AMWA Budapest Working Group Oversight Review Team, with special responsibility for the area of transparency and public disclosure in relation to clinical-regulatory documents.

DDF37 Personal Data Protection in the Clinical Trial Disclosure Era

Profile: This workshop is for medical writers at different stages of their career. There is no prerequisite for participation but a basic knowledge of clinical trial documents is expected.

Objective: The EU Clinical Trial Regulation (CTR) and the EMA Policy 0070 require public disclosure of clinical trial (CT) documents. The EU General Data Protection Regulations (GDPR) requires that personal data in these documents be protected. Though divergent at first glance, these new sets of requirements are actually aligned to benefit patients. As medical writers, we need to find the right balance between disclosure and data protection while maintaining the scientific utility of the documents we write. The objective of this workshop is to help medical writers deal with different CT documents impacted by requirements for transparency and public disclosure and the GDPR. The participant will gain knowledge in identifying critical patient data and the "risk areas" of a CT document or project, and in mitigating risks to confidentiality and compliance.

Content: The workshop will cover:
· a short introduction to CT transparency and disclosure, the key regulations (i.e., EU CTR, EMA Policy 0070, GDPR), and definitions of key terms
· Benefits, challenges, and risks of public disclosure
· CT documents impacted, with focus on the study protocol and the clinical study report
· Personal data pseudonymisation ("redaction-friendly") techniques at the document level
· Working with other functional groups to ensure patient data protection in CT documents
· Real life examples
· Hands on exercises

Raquel Billiones

Raquel Billiones has a PhD in Biology and more than 25 years combined experience in scientific and clinical research. She has been a medical writer for >15 years, with core competencies in writing clinical trial and regulatory documents for pharmaceuticals and medical devices. Her experience also includes transparency,

disclosure and patient data protection in clinical trial data reporting. Over the years, she took on a wide range of industry positions, as freelancer, employed regulatory writer, and as head of medical writing departments in the CRO and big pharma settings. Raquel is an active member of EMWA, serving in various roles, including
•Medical Writing editorial board member since 2010, currently Editor-in-Chief
•Education Committee member and workshop leader
•Co-founder of the SIGs on Medical Devices and on Sustainability.

DDF38 CORE Reference - Clarity and Openness in Reporting: E3-based

Profile: Regulatory medical writers working in the contract research organisation or pharmaceutical company environment, as either employees or as freelancers, who write or review clinical study reports (CSRs). The workshop will meet the needs of writers and reviewers in interpreting existing International Council for Harmonisation (ICH) guidelines that drive preparation of CSRs, and in ensuring that CSRs are written in accordance with the principles of responsible clinical trial data sharing. There are no prerequisite EMWA workshops for attendance at this workshop.

Objective: The current ICH guidance on CSR authoring is ICH E3 (1995) and the 2012 Questions and Answers (Q & A) Revision document. Inconsistencies in interpretation require clarification, and indeed this is recognised specifically for ICH E3 in the 2012 Q & A document. CORE Reference (see http://www.core-reference.org/) launched on 03 May 2016, provides interpretational guidance on CSR authoring that incorporates regional (EU and US) and real-world insights. These include guidance on writing CSRs that share clinical trial data responsibly, and in accordance with current public disclosure requirements. Participants will acquire the knowledge and skills required to author or review fit-for-purpose CSRs that belong in the modern drug development arena.

Content:

- Background to CORE Reference
- Description of CORE Reference complete web-based resource
- Common inconsistencies in ICH guideline interpretation and how CORE Reference addresses these issues
- Background to transparency and public disclosure requirements
- How CORE Reference deals with the challenges of responsible clinical trial data sharing.

Sam Hamilton

Sam Hamilton is a postdoctoral virologist, with 28 years in clinical and regulatory medical writing and leadership roles in the pharmaceutical industry. Sam has a special interest in public disclosure of clinical-regulatory documents as Chair of the EMWA-AMWA group who delivered the open-access www.core-reference.org in May

2016. Sam is long-time supporter of EMWA serving in various roles over 15 years, notably as Freelance Advocate; Editorial Board member for Medical Writing (MEW); Workshop Leader; Expert Seminar Series (ESS) Chair; and Vice President and President. Sam was elected an EMWA Nick Thompson Fellow in 2018 for her services to the Association. Sam is currently MEW Section Editor for the "Regulatory Public Disclosure" Section, and Chair of The CORE Reference Project.

Tracy Farrow

Tracy is currently Executive Director, Medical Writing and Healthcare Communications for Evidera where she provides senior-direction and decision making to a global team of medical writing professionals who deliver document development services across the spectrum of peri- and post-approval studies, and strategic writing services including study documents, manuscripts, publication planning, and posters. Tracy has more than 25 years of Biomedical Science experience. Prior to joining Evidera, Tracy was employed by Evidera's parent company PPD. Her roles included senior director, director, and associate director with operational responsibilities over clinical medical writing teams. Prior to joining the medical writing group at PPD, Tracy served as a manager of medical writing services for ClinTec International Ltd.; and Pfizer as Medical Writing Therapeutic Area Lead, and Quality Manager for Data Management where she was responsible for data privacy training, audit management, SOP and best practice development. She lectured in Intermediate Laboratory Data Management for the Association for Clinical Data Management for a number of years as part of their professional development program. She attained her 2.1 (Hons) GI Biol in Biochemistry in 1993 after gaining two Higher National Certificates in Haematology and Chemistry. Tracy is the Co-Chair of the EMWA Regulatory Public Disclosure Special Interest Group and is an active contributor to EMWA. From May 2014, Tracy has been a member of the EMWA-AMWA Budapest Working Group Oversight Review Team, with special responsibility for the area of transparency and public disclosure in relation to clinical-regulatory documents.

DDF38a CORE Reference - Clarity and Openness in Reporting: E3-based

Profile: Regulatory medical writers working in the contract research organisation or pharmaceutical company environment, as either employees or as freelancers, who write or review clinical study reports (CSRs). The workshop will meet the needs of writers and reviewers in interpreting existing International Council for Harmonisation (ICH) guidelines that drive preparation of CSRs, and in ensuring that CSRs are written in accordance with the principles of responsible clinical trial data sharing. Participants must have written at least one CSR or reviewed several, and have

working knowledge of International Council for Harmonisation (ICH) reporting guidelines.

Objective: The current ICH guidance on CSR authoring is ICH E3 (1995) and the 2012 Questions and Answers (Q & A) Revision document. Inconsistencies in interpretation require clarification, and indeed this is recognised specifically for ICH E3 in the 2012 Q & A document. CORE Reference (see http://www.core-reference.org/) launched on 03 May 2016, provides interpretational guidance on CSR authoring that incorporates regional (EU and US) and real-world insights. These include guidance on writing CSRs that share clinical trial data responsibly, and in accordance with current public disclosure requirements. Participants will acquire the knowledge and skills required to author or review fit-for-purpose CSRs that belong in the modern drug development arena.

Content:

· Background to CORE Reference· Description of CORE Reference complete web-based resource
· Common inconsistencies in ICH guideline interpretation and how CORE Reference addresses these issues
· Background to transparency and public disclosure requirements
· How CORE Reference deals with the challenges of responsible clinical trial data sharing.

Sam Hamilton

Sam Hamilton is a postdoctoral virologist, with 28 years in clinical and regulatory medical writing and leadership roles in the pharmaceutical industry. Sam has a special interest in public disclosure of clinical-regulatory documents as Chair of the EMWA-AMWA group who delivered the open-access www.core-reference.org in May 2016. Sam is long-time supporter of EMWA serving in various roles over 15 years, notably as Freelance Advocate; Editorial Board member for Medical Writing (MEW); Workshop Leader; Expert Seminar Series (ESS) Chair; and Vice President and President. Sam was elected an EMWA Nick Thompson Fellow in 2018 for her services to the Association. Sam is currently MEW Section Editor for the "Regulatory Public Disclosure" Section, and Chair of The CORE Reference Project.

Vivien Fagan

Vivien has 27 years of experience in an international pharmaceutical CRO of which 24 have been in clinical and regulatory medical writing. In her current position as Director, Global Medical Writing and Head of IQVIA's Clinical Trial Disclosure group, Vivien manages a team of UK and European Medical Writers along with a group of Clinical Trial Disclosure Specialists based out of India. Vivien was a member of the EMWA-AMWA group who delivered the open-access www.core-reference.org in May 2016. On the topic of CORE Reference, Vivien is an EMWA Workshop Leader, DIA panellist and a member of The CORE Reference Project committee. In more recent

years, Vivien has been an Expert Seminar Series (ESS) presenter on the topic of the EU CTR/CTIS.

DDF39 An Overview of Healthy Volunteer Studies

Profile: This workshop is for medical writers who would like to gain insight into the unique aspects of clinical trials conducted with healthy volunteers rather than patients (such as Phase 1, thorough QT, and bioequivalence studies).

Objective: Healthy volunteer studies make up a large proportion of studies in most clinical development programmes. Medical writers working on documents for these studies need to understand how they differ from clinical trials in patients. After attending this workshop, the participant will understand the design issues and data collected in healthy volunteer studies.

Content: This workshop will cover the following topics for healthy volunteer studies:

- Key regulatory guidance documents
- Populations studied
- Study designs and objectives
- Types of assessments

Note: Phase I studies in patients will not be covered.

Note: Content in this workshop was previously included in Workshop DDA18. (Medical Writing for Healthy Volunteer Studies)

Anne McDonough

Anne is a medical writer with over 25 years of experience in a wide variety of therapeutic areas for clients ranging from emergent biopharma companies to multinational corporations. She has worked in a number of research roles (writing, clinical science, operations, compliance, and training) and has settled on medical writing as the most enjoyable of them. Her experience includes dozens of healthy volunteer studies (PK/PD, microdosing, thorough QT, food effect, bridging, etc.). Anne writes across the continuum of clinical research from operational documents to clinical study reports, nonclinical and clinical CTD modules, and manuscripts. She has also worked with nonprofit organisations and academia on conference reports, manuscripts, clinical support tools, and training and evaluation materials.

DDF4 The Patient Information Leaflet

Profile: This workshop is aimed at all medical writers, including native English speakers, who would like to develop their skills and awareness when writing information for patients.

Objective: The vocabulary and style that medical writers normally use for communicating with a scientifically educated audience are not always appropriate for communicating with the public. The purpose of this workshop is to guide medical writers to view their use of language from a patient's perspective. Clinical trial Patient Information Leaflets (informed consent documents) will be used to structure the workshop, however, the principles apply to most written communications with the public. On completion of the workshop package, participants should be able to write a patient information leaflet suitable for use in a clinical trial.

Content: The workshop will start with some information about the content of Patient Information Leaflets, including regulations and other important sources of elements of informed consent. The workshop will continue with some guidance on style and communicating with patients. Particular emphasis will be placed on identifying and avoiding jargon. Workshop exercises will be used to practice modifying typical source information into wording suitable for inclusion in a Patient Information Leaflet. There will be some discussion about obtaining informed consent in special cases, and common questions that arise.

Wendy Kingdom

Wendy has more than 30 years' experience of clinical research and medical writing in the pharmaceutical industry. She started her career as a clinical research associate; writing protocols, preparing related study documents, managing studies, and writing clinical study reports. She has been working successfully as a freelance medical writer since 2002 and specialises in clinical and regulatory documents. She has provided commercial and academic training on medical writing. Wendy was EMWA Education Officer 2003–2005, served on the EMWA Professional Development Committee (EPDC) for 5 years, and was Treasurer of EMWA from 2005–2009.

DDF41 Writing a Clinical Study Protocol

Profile: This workshop is aimed at new medical writers and experienced writers who are new to writing clinical study protocols.

Objective: The purpose of this workshop is to introduce medical writers to the components and concepts of a protocol, and to provide instruction on protocol writing. On completion of the workshop package, participants should feel confident about how to develop and write a protocol and how to manage the process.

Content: The workshop will explain how to develop a protocol with practical examples and exercises. Participants will be introduced to the role of the study team in protocol writing. An outline will be given of regulations, guidelines, and sources of information. The pre-workshop assignment will be reviewed and used to build up a picture of the study. The influence of the study design on the protocol will be discussed. Development of the protocol synopsis will then be examined in detail,

including discussion of study design and the relationship of the protocol with the Case Report Form.
The workshop will then focus on the body of the protocol, i.e. filling in the details, including how to ensure that the study will be conducted as intended. This will be supplemented by the interactive workshop exercises, which are designed to get participants thinking in logical, practical sequence. The last part of the workshop will describe the 'standard' and administrative sections, appendices, and the 'When, Why and How?' of protocol amendments.

The workshop will then focus on the body of the protocol, i.e. filling in the details, including how to ensure that the study will be conducted as intended. This will be supplemented by the interactive workshop exercises, which are designed to get participants thinking in logical, practical sequence. The last part of the workshop will describe the 'standard' and administrative sections, appendices, and the 'When, Why and How?' of protocol amendments.

Debbie Jordan

Debbie has been working in the pharmaceutical industry for over 30 years in both pharmaceutical company and CRO environments. She has worked as a data assistant, CRA and project manager, before moving into medical writing. Twenty years ago she set up her own medical writing company and now works on all aspects of medical writing from clinical development programmes and regulatory packages through to marketing and conference material. Debbie also provides training in medical writing and associated topics to a variety of organisations. Debbie has served on the Executive Committee of EMWA in the past and was a key member of the CORE reference working group.

Wendy Kingdom

Wendy has more than 30 years' experience of clinical research and medical writing in the pharmaceutical industry. She started her career as a clinical research associate; writing protocols, preparing related study documents, managing studies, and writing clinical study reports. She has been working successfully as a freelance medical writer since 2002 and specialises in clinical and regulatory documents. She has provided commercial and academic training on medical writing. Wendy was EMWA Education Officer 2003–2005, served on the EMWA Professional Development Committee (EPDC) for 5 years, and was Treasurer of EMWA from 2005–2009.

DDF48 Consistency Within and Across Regulatory Documents: Writing and Managing VIRTUAL WORKSHOP

Profile: This workshop is intended for writers who have basic experience in regulatory medical writing (RMW) and an interest in document consistency and

project management. Writers without previous RMW experience could also benefit from this workshop after completing one additional pre-workshop requirement.

Objective: This workshop aims to demonstrate what consistency is, how writers can recognize and avoid inconsistencies, and provide tips for project management in large-team submission projects. Following this workshop, participants should be able to recognize the different types of consistency, identify inconsistencies and avoid/correct them, and manage demanding submission projects (including timelines) with more confidence and competence.

Content: The workshop will give good and bad examples of document consistency and demonstrate how writers can recognize and avoid/correct inconsistencies; present advice for improving inter- and intra-document consistency; use examples from submission projects to explain strategies for consistent complex documents; provide project management tips to help face the challenges of working in large teams of writers and reviewers; provide tips for better team communication and timelines management.

Kleopatra Kouroupaki

Kleopatra is a physicist, with an MSc in Neuroscience and a PhD in Neurophysiology. She started her career 12 years ago with ambition to become a scientist: initially by teaching mathematics and physics and later by working as an electrophysiologist in brain research. After completing her PhD, academia forced her to seek alternatives. Every road led to medical writing. She works at Trilogy Writing & Consulting and has taken part in complex submission projects. She primarily works on CTDs, as well as on CSRs and other clinical documents for various indications. She has been a member of EMWA since 2015.

DDF49 Public Clinical Trial Registries: Results Reporting Requirements and Practical Demonstration

Profile: This workshop is intended for participants wishing to learn about the requirements, timings, and processes for disclosure of clinical trial results in public databases in the US (ClinicalTrials.gov) and EU (EudraCT). Also presented will be implications of the Regulation EU 536/2014 and its portal Clinical Trials Information System (CTIS); differences between EudraCT and CTIS will be highlighted. Understanding basic clinical development stages and knowledge of regulatory documents (clinical study protocol, clinical study report, and statistical analysis plan) are essential. Previous experience in clinical trial results disclosure is not required.

Content: The workshop will contain the following:
i) brief Q&A session on legal regulations and non-legal requirements governing results disclosure for the US and EU

ii) summary of the requirements and content of the US and EU clinical trial results records
iii) brief introduction to CTIS; explain differences between EudraCT and CTIS
iv) practical tips on how to approach authoring of the results entries
v) live presentation of the database structure and study results entry
vi) considerations and implications for medical writers preparing results records, with practical examples

Holly Hanson

Holly gained her PhD in drug metabolism at the University of Manchester and BSc in pharmacology/physiology at the University of Sheffield. Having initially trained as a pharmacokineticist when her career in clinical research began in 2001, Holly's passion for writing saw her transition to Medical Writing in 2007. Holly's experience includes writing Clinical Study Reports, Clinical Study Protocols, Protocol Amendments, Development Safety Update Reports, Patient safety narratives and public disclosure of clinical trial results. Holly's areas of expertise are Phase I/II clinical studies and public disclosure of clinical trial results. Holly is co-Chair of the EMWA Regulatory Public Disclosure Special Interest Group. Currently, Holly is the Director of Trial Transparency at BioNTech.

Kathy Thomas-Urban

Kathy B. Thomas, PhD is an independent consultant and medical writer with more than 20 years of experience in the pharmaceutical industry and academia, and with extensive knowledge of clinical trial disclosure law in the US and EU. She has worked on preparing registry entries and developing internal guidelines and processes to assure compliance. Kathy has been part of the clinical trial disclosure and transparency landscape and has frequently updated EMWA members about this fast-evolving topic through symposia presentation and publications. Kathy is an active core team member of the EMWA Regulatory Public Disclosure Special Interest Group and also of the DIA Special Interest Group on disclosure and transparency.

Previously, Kathy served as the Head of Medical Writing at Altana Pharma AG in Konstanz, Germany. Kathy has a thorough knowledge of documents and processes related to the preparation of regulatory documents and disclosure/transparency activities whether at a pharmaceutical company or a CRO.

DDF5 Clinical Study Report Appendices

Profile: Medical writers working in the clinical research organisation or pharmaceutical company environment, as either employees or as freelancers. The workshop will meet the needs of writers tasked with preparing or performing quality control checks on appendices for clinical study reports (CSRs). This is an ideal forum for writers whose organisations or clients provide little guidance on appendix requirements, beyond provision of 'ICH Guideline E3: Structure and content of

clinical study reports' and, further, may facilitate improvement in existing analysis and reporting processes and procedures.

Objective: The integrated CSR is a multi-component document comprising a text-based report and associated appendices. The text-based sections of the CSR are often given prominence and priority over the appendices, leaving the medical writer with insufficient time and resources to complete this necessary component of a full, integrated CSR. The workshop discusses time-planning and proactivity for appendices compilation as well as all the contents of Section 14 plus Appendices 16.1 to 16.4 inclusive. After completing the workshop, participants will understand how to best schedule appendices compilation and will understand the necessary content of each individual appendix.

Content: The following topics will be covered:

- Why prepare CSR appendices?
- Requirements for ICH E3 Section 14 Appendices 16.1 - 16.4, adapted for MAAs (content in theory)
- Hierarchical appendix filling structure
- Time-planning for appendices compilation
- Managing and tracking appendices contents
- Set up of a hierarchical appendix filing structure

Requirements for ICH E3 Section 14 Appendices 16.1 - 16.4, adapted for MAAs (content in practice)

- Communication and management
- Scheduling appendices
- Narratives: administrative and management aspects
- Appendices for abbreviated CSRs
- Electronic transfer of appendices
- Appendices for device and observational study reports

Sam Hamilton

Sam Hamilton is a postdoctoral virologist, with 28 years in clinical and regulatory medical writing and leadership roles in the pharmaceutical industry. Sam has a special interest in public disclosure of clinical-regulatory documents as Chair of the EMWA-AMWA group who delivered the open-access www.core-reference.org in May 2016. Sam is long-time supporter of EMWA serving in various roles over 15 years, notably as Freelance Advocate; Editorial Board member for Medical Writing (MEW); Workshop Leader; Expert Seminar Series (ESS) Chair; and Vice President and President. Sam was elected an EMWA Nick Thompson Fellow in 2018 for her services to the Association. Sam is currently MEW Section Editor for the "Regulatory Public Disclosure" Section, and Chair of The CORE Reference Project.

DDF50 A Beginner's Guide to Key Clinical Documents in the EU Drug Development Process

Profile: This introductory workshop is designed for participants with little or no experience of the drug development process or the regulatory documents required.

Objective: The objective of this workshop is to give new medical writers an overview of the drug development process and the key clinical and regulatory documents commonly required in the EU. The workshop will provide a high level guide to these documents, including their purpose, target audience, the applicable regulatory guidelines, and additional resources (templates, style guides, etc.) that can help new writers prepare these documents.
At the end of this workshop participants will be able to better appreciate the range of regulatory documents and understand how they fit into the different phases of drug development.

Content: The following documents will be described in the order they are needed in drug development:

1. Clinical Trials
- Investigator's brochure (IB)
- Investigational medicinal product dossier (IMPD)
- Clinical study protocol (CSP) and synopsis
- Patient information and informed consent forms (ICF)
- Clinical study report (CSR)
- Lay summary of clinical trial results

2. Clinical Development and Regulatory Strategy
- Paediatric investigation plan (PIP)
- Orphan drug application (ODA)

3. Marketing Authorisation Application
- Common technical document (CTD) clinical modules
- Summary of product characteristics (SmPC)
- Package leaflet

4. Post Approval documents
- Redaction package

For each document, the following will be summarised:

- Who will use it and how it will be used
- Who is involved in its preparation and what is the role of the medical writer
- Where the information in each document comes from
- How it fits with the other documents during drug development
- What are the applicable regulatory guidelines, template(s) and styles used

Abraham Fred Shevack

Abe F. Shevack MA, ELS is a Biologist with many years of experience in basic research in both academia and industry. He is also a certified Editor in the Life

Sciences. For over 20 years as a senior scientific medical writer at Schering and Bayer, Abe wrote numerous regulatory documents including clinical study protocols, investigator's brochures, study reports, and CTD documents for global regulatory submissions. He has worked in a wide range of therapeutic indications and has participated in successful global marketing authorizations for new drugs in leukemia, non-Hodgkin's lymphoma, hepatic cell carcinoma, macular degeneration, and men's health. Since 2016, Abe has been the owner of Associated Medical Writer Services where he writes and consults for clients in pharma and biotech. He has been a member of EMWA since 1996 and is a past-President (2017-2018) and workshop leader. He is currently the chair of the EMWA Ambassador's Programme.

Raquel Billiones

Raquel Billiones has a PhD in Biology and more than 25 years combined experience in scientific and clinical research. She has been a medical writer for >15 years, with core competencies in writing clinical trial and regulatory documents for pharmaceuticals and medical devices. Her experience also includes transparency, disclosure and patient data protection in clinical trial data reporting. Over the years, she took on a wide range of industry positions, as freelancer, employed regulatory writer, and as head of medical writing departments in the CRO and big pharma settings. Raquel is an active member of EMWA, serving in various roles, including
•Medical Writing editorial board member since 2010, currently Editor-in-Chief
•Education Committee member and workshop leader
•Co-founder of the SIGs on Medical Devices and on Sustainability.

DDF51 Basics of Veterinary Regulatory Affairs

Profile: This workshop is aimed at medical writers, both new and experienced, who would like to improve their understanding of veterinary regulatory affairs. This is a foundation level workshop. No previous knowledge of veterinary regulatory affairs is assumed, but experience in the Market Authorisation of pharmaceuticals would be helpful. This workshop is expected to be of benefit for personnel working in Regulatory Affairs, Research and Development, Clinical Trials and Marketing.

Objective: Workshop participants will be introduced to the field of veterinary regulatory affairs. A short introduction to the EU Regulatory Framework and different legal routes (procedures) and legal bases to authorisation will be followed by an overview of the basic content and structure of a typical dossier for Veterinary Medicinal Products (VMPs). Veterinary regulatory documents to be written by medical writers will be discussed. Participants will gain a good broad understanding of this area of regulatory affairs, which they can use to their benefit when working in this area.

Content:

- Overview of current and future EU VMP regulatory framework
- EU Marketing Authorisation procedures
- Structure and content of a VMP dossier
- Other veterinary regulatory documents

The topics above will be covered by initially presenting the information, followed by interactive question and answer sessions which will allow everyone to participate.

Karolina Bate

Karolina Bate has worked for Cyton Biosciences, a veterinary regulatory consultancy, for 13 years, with the last 5 years in the role of Managing Director. As Managing Director, Karolina is responsible for the strategic regulatory oversight for all pharmaceutical and immunological projects. Karolina also provides EU veterinary regulatory training for animal health companies in various different subjects within the regulatory field.

DDF52 Veterinary Guide to One Health and Opportunities for Medical Writers/Communicators

Profile: This workshop is aimed at medical writers, both new and experienced, who would like to improve their understanding of One Health. This is a foundation level workshop. No previous knowledge of One Health is assumed, but experience would be helpful for group work and discussion.

Objective: The workshop is expected to be of benefit to medical writers coming in touch with One Health topics such as antimicrobial resistance, zoonoses, comparative or translational medicine, and food safety.

Content: One Health is a transdisciplinary approach to human, animal and environmental health.In 1858 Rudulf Virchow noted that "Between animal and human medicine, there are no dividing lines – nor should there be. The object is different, but the experience obtained constitutes the basis of all medicine". Today, 60% of existing human infectious diseases are zoonotic, and 75% of emerging diseases of humans (including Ebola, HIV, Influenza) have an animal origin. Workshop participants will be introduced to the definition and history of One Health. Particular emphasis will be on Zoonoses, Public Health, Comparative and Translational Medicine and Microbiology. Examples of zoonoses, emerging infectious diseases of animal origin and also antimicrobial resistance will be used to illustrate how human health can be impacted and participants will have the opportunity to discuss these along with the emerging opportunities for medical writers/ communicators. Participants will gain a broad understanding of One Health topics linking human and animal health, which they can use when working in this area.

Kilian Unger

Kilian Unger is a veterinarian who has worked for many years as a veterinary public health specialist with the Department of Agriculture's State Veterinary Service (SVS) in Ireland. He started life working in private practice before joining the SVS as a veterinary inspector and spent the first few years supervising the application of official controls on food safety, animal health and animal welfare in meat plant establishments. For over 15 years he has specialised in Veterinary Public Health Policy with particular emphasis on food safety and zoonoses. He been centrally involved in policy matters relating to the monitoring and control of *Salmonella* in pigs and poultry and *Campylobacter* in broilers. He represented Ireland at national and international forums including EU Commission working group and Standing Committee meetings, the EFSA network on Zoonoses Monitoring Data Collection and the annual FAO/WHO Codex Committee meeting on Food Hygiene.

DDF53 A Medical Writer's Guide to Collaborative Authoring

Profile: This workshop would benefit all medical writers currently working in regulatory writing. There are no prerequisites for this workshop.
Complementary EMWA workshops include: How to Manage your Writing Project (PTF29), Interpersonal Skills for Medical Writers (PTA12), Establishing Effective Review Practices for Regulatory Documents (PTA15), and Building Medical Writing Teams (PTA14).

Objective: In addition to the task of medical writing we are more and more frequently called to author documents in a more collegiate atmosphere, writing directly as part of a team who all have access to the working document during drafting. This workshop aims to equip the regulatory medical writer with the understanding and skill sets necessary to manage and work optimally within teams in this collaborative fashion. This workshop will help regulatory medical writers realise the advantages of writing collaboratively and develop the soft skills to successfully orchestrate a group of collaborators.

Content: In this workshop we will cover:

- Why we are moving towards collaborative authoring and what this means for the medical writer
- Optimal strategies for planning and commencing a collaboration project
- How to effectively use the expertise of your team
- How to assess and manage your collaboration team
- How to achieve agreement during authoring to optimise review cycles

- The technical tools: different means of collaboration
- How to overcome fear: understanding the technical process and optimising the document production cycle
- Learning from each collaboration project and improving the next one

Sarah Tilly

Sarah values the people with whom she writes in the same way she values the patients about whom she writes, and the customers for whom she writes. She believes that everyone has their own, unique contribution to give to our industry. For this reason, Sarah has been involved in mentoring new medical writers since an early stage of her career. In parallel with her largely regulatory writing experience, she has managed and mentored several teams of writers and has been involved in setting up and coordinating training systems. Sarah has been medical writing since 2006 in clinical research organisations and medical writing consultancies. She set up Azur Health Science in 2017 as Medical Writer and Director. She holds a first degree in Biology and a PGCert in International HTA, Pricing and Reimbursement.

DDF54 Non-Clinical Study Reports

Profile: The non-clinical study report (NCSR) is a comprehensive document that presents the findings and results of studies conducted on substances or products in preclinical or laboratory settings. Hence, those who stand to benefit from this workshop are regulatory personnel and scientific/medical writers in the pharmaceutical industry, those at CROs or medical writing agencies involved in regulatory documentation, or within academic groups/technology transfer departments at universities, etc.

Participants of this workshop will be expected to have basic experience/knowledge of the drug development and approval process in the US and/or the EU, as well as familiarity with various components of the eCTD.

Objective: Participants of this workshop will receive an overview of the regulatory guidelines and individual parts of the NCSR and relevant source documents, as well as submission requirements. Thereby, the medical writer's role in the preparation of the NCSRs will be highlighted.

Content: Non-clinical studies are a crucial element of the drug development process and are typically performed before any testing on human subjects (clinical trials). Non-clinical study reports summarise the development, safety, efficacy, and potential risks associated with a substance or product under investigation.

The main focus of the workshop will be to clarify the medical writer's role in the selection and assembly of relevant source documents when preparing an NCSR.

The workshop is planned to be interactive and will include discussion of participants' questions submitted in their pre-workshop assignments as well as group activities throughout the workshop.

Carola Krause

Based in Potsdam, Germany, Carola Krause has been offering a professional biomedical writing consultancy service to the pharmaceutical industry since 2016. Carola is a postdoctoral molecular cell biologist with hands-on experience in basic and pharmaceutical research and development. Her multidisciplinary background in academic and pharmaceutical project management and clinical trial coordination provides her with key insights into all phases of the drug development process and its regulatory requirements. She has 15 years of experience in biomedical communication and has attended EMWA workshops since 2014. Carola is the chair of EMWA's Creative team, co-founded the Sustainability Special Interest Group and has served as EMWA's (Vice)President from 2020–2022.

Sally Hill

Sally is based in the Netherlands where she works as Senior Scientific Writer at a small Utrecht-based biotechnology company. Her background includes experience in the lab as a molecular biologist, in the classroom as a university lecturer in scientific writing, and in consultancy as a translator/editor/writer of medical and scientific texts. Sally's recent move into the pharmaceutical industry has given her a deep dive into non-clinical writing and regulatory submissions within oncology. A longstanding member of EMWA and a keen networker, she has helped to set up a Dutch network of scientific and medical writers and is an active participant of EMWA's Regulatory Special Interest Group. She also serves as Chair of SENSE, the Society of English-language professionals in the Netherlands.

DDF6b From Protocol to Study Report: What's In-between?

Profile: This workshop is designed for medical writers who are new in the field of regulatory writing and clinical development. The workshop will provide an overview of the conduct of a clinical trial. Although the workshop does not go into detail about each of the topics addressed, it will serve as a basis for more specialised workshops.

Objective: After the workshop the participants should have an understanding of how a clinical study is conducted and how individual patient data collected at an investigational site are converted into the study results. This workshop aims to provide an overview of the different steps of a clinical trial (clinical phase, data management, statistical analysis) with an emphasis on the handling of patient data.

Based on this overview a medical writer should be able to improve the description of study conduct and study results in an integrated study report.

Content: Based on pre-workshop reading of the most relevant ICH guidelines, the different steps of a clinical trial will be discussed. This will include the clinical phase (basic regulatory requirements, monitoring), data management (data entry, data cleaning, coding, electronic data capture) and statistics (analysis plan, steps of analysis). The flow of data from the investigational site to the study report will be summarised. Participants will identify relevant information needed for the preparation of a study report.

Franziska Pirkl

Franziska has worked in the field of protein biochemistry before she decided to become a medical writer at an international Contract Research Organisation in 2001. She has gained considerable experience in preparing study protocols, study reports, CTD clinical summaries and overviews, and publications. Franziska has also been involved in pharmacovigilance writing, managed large medical writing projects and trained medical writers. Her writing projects have covered a wide range of therapeutic areas including cardiology, dermatology, endocrinology, gastroenterology, immunology, musculoskeletal disorders, neurology, oncology, ophthalmology, pulmonary/respiratory diseases, and rheumatology. In 2011, Franziska joined Kantar Health, Clinical & Real World Research, where she now leads the medical writing team.

DDF7 Introduction to Pharmacokinetics

Profile: This workshop is aimed at medical writers, both new and experienced, who need to understand the basics of pharmacokinetics. Participants will normally have had little if any previous formal instruction in pharmacokinetics, or may not have understood what instruction they have received (or may even have received such instruction before they realised they would need it).

Objective: The objective of this workshop is to demystify pharmacokinetics for those who are terrified of mathematics. On completing the workshop participants should understand the meanings of some of the key terms and symbols used in pharmacokinetics, have some understanding of what the different terms tell us about the properties of drugs and be able to write competently about basic pharmacokinetics.

Content: Participants will be given straightforward explanations and derivations of the key pharmacokinetic principles and equations. These explanations will be largely conceptual rather than mathematical, with worrisome mathematical terms and techniques explained in simple terms.

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John Carpenter

John, a pharmacologist, was a lecturer in pharmacology at Manchester University from 1974 to 1992, where he studied drugs and the movement of ova through oviducts, anti-asthma drug models, and the pharmacokinetics of alcohol (never a shortage of volunteers). He has written or contributed to several pharmacology textbooks, and acted as an expert witness in court cases involving alcohol. In 1992, he became a full-time medical writer, initially with Gardiner-Caldwell Communications, then as Medical Team Director at Medical Action Communications and briefly as Medical Director at OCC. Since 2001, he has been a freelance medical writer, medical communications consultant, and trainer. John is a regular contributor to the range of training courses offered by the Proper Medical Writing Group in Poland and by Kemic Bioresearch in Canada. Satisfied customers include the Canadian Government's medicines regulatory department. He has served on the EMWA Executive Committee as Universities Liaison Officer and was a member of the EMWA Professional Development Committee (EPDC) from 2005 to 2010.

LWA11a Tense

Profile: This workshop is targeted towards medical writers whose native language is not English. Native speakers who encounter difficulties with the use of tense or who need to be aware of the difficulties experienced by non-native English writers in this area are also welcome.

Objective: Provide guidance for medical writers who are not native speakers of English on the effective use of tense in English scientific and medical texts.

Content: The use of tense in English is a major problem area for medical writers whose first language is not English. This workshop will focus on the proper use of tense as a key element in meaning in our types of text. Examples of typical problems are distinguishing between the simple past and present perfect, choosing the right tense for generally valid statements, correctly applying different forms of present and future tenses, and the appropriate use of modal verbs. Based on the presentations and hands-on exercises, we will look at the different tenses used in different sections of study protocols, study reports and other documents typically prepared by medical writers. More exercises will show us how some tenses are more suitable when speaking and some more suitable when writing.

For the pre-workshop assignment, participants will be required to submit particular problems with tense they encounter when working with medical documents in English. The workshop leaders will analyse and discuss selected topics from the participants' pre-workshop assignments during the workshop. Exercises based on these examples will give participants the opportunity to discuss solutions amongst themselves and with the workshop leaders. The post-workshop assignment will consolidate the content of the workshop.

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Johanna Chester

LWA12 Master Class: Taxonomic Analysis of Medical Writing

Profile: Experienced medical writers.

Objective: To enhance the identification, analysis, and revision of syntactic writing distractions.

Content: Do you want to enhance your copyediting skills with a systematic approach? If so, the following steps in the analysis of 24 sets of sentences have been shown to be effective. **First** as a pre-workshop assignment, select the clearer sentence in each set; that is, the one free of a syntactic distraction which you will describe by your own distraction nomenclature (e.g.,wordiness). **Second** from a compilation of the preworkshop assignments from all workshop enrollees prepare to present the selection and nomenclature for two assigned sets. **Third**, as a member of a clarity-testing panel, listen to the comments of other members and the workshop leader who will provide systematic nomenclature. **Fourth**, as a post-workshop assignment, send a list of sentences indicating any change of selection and/or nomenclature. **Fifth**, receive feedback from the workshop leader about your selections and nomenclature.

Michael L Schneir

Michael, a professor in biochemistry, teaches research writing to graduate students and residents. His current research is to determine distractions of clarity in medical writing by focusing on distraction identification at different textual levels (intra- and inter-sentence) and on their syntactic taxonomic classification. The intent is to transform intuitive copyediting into systematic analysis.

LWA14 Master Class - The Medical Journal Article: Section-Specific Distractions

Profile: This workshop, at an advanced level, is accessible to all medical writers interested in the journal article and syntactic clarity.

Objective: To enhance understanding the writing distractions pertinent to conceptual components of the journal article. The distractions are focused on syntactic intra-sentence structure and order of words, phrases, and clauses.

Content: By the following 3-levels of activities, gain insight into syntactic distractions that are specific for the conceptual components of the medical journal article.
(1) Pre-workshop: Complete a clarity-testing exercise. That is, from each of 12+ sets of paired sentences, select the clearer sentence and describe the primary distraction in the unselected sentence. After sending your selections (and justifications) and then receiving a guide to structure and order syntactic distractions, prepare to participate in the workshop.
(2) Workshop: For each set in the clarity-testing exercise, participate in a discussion with other registrants and the workshop facilitator. After the discussion of each set, the workshop facilitator will analyze and justify his decision, after which the vote tally will be revealed and followed by more discussion.
(3) Post-workshop: Comment on the distractions and revisions with which you still disagree.

Michael L Schneir

Michael, a professor in biochemistry, teaches research writing to graduate students and residents. His current research is to determine distractions of clarity in medical writing by focusing on distraction identification at different textual levels (intra- and inter-sentence) and on their syntactic taxonomic classification. The intent is to transform intuitive copyediting into systematic analysis.

LWA4 Beyond Simple Editing

Profile: Experienced medical writers or editors who are ready to move into a more senior role. Participants should be competent in editing for style and formatting and in basic language editing.

Objective: To consider the elements of in-depth editing – that is, editing that involves revising a piece of text to maximise its effectiveness.

Content: We will briefly review the elements of editing and then consider how in-depth editing can improve the quality of a document. Participants will carefully examine a piece of text using questions raised as part of the pre-workshop assignment. We will then discuss how the text could be revised, and what should be prioritised if working to a deadline. Exercises will focus on parts of the document and participants will complete the revisions as part of the post-workshop assignment. The workshop will be interactive, with time for the participants to share their experience. The focus of the workshop is on decision making and not on tools to support editing, although those may come up in our group discussions.

Barbara Grossman

Barbara Grossman has a passion for proofreading, quality control, and education. She started Hawkeye Medical Limited, a medical writing and consultancy business, after working for a medical publishing company and then a contract research

organisation, where she built up and managed its medical writing group. Barbara runs professional development training for companies and educational institutions. She has had many roles in EMWA: workshop leader since 2001, Treasurer 1998–2005, member of the Education Committee 2010–2018, Education Officer 2014–2016. She was awarded an EMWA fellowship in 2005 and is a past EMWA President. In addition, Barbara is an Associate Editor of *Medical Writing*, EMWA's journal.

Marian Hodges

Marian is a publishing consultant, with particular interests in training and preparing clear content tailored for the audience. Until April 2018, Marian was Associate Director for Publishing at the UK's National Institute for Health and Care Excellence, where she built up and managed the editorial and digital publishing teams. Marian set up EMWA's first website in 1997, and was awarded an EMWA fellowship in 2007. With Barbara Grossman, she has run over 60 EMWA workshops. Marian served on the Executive Committee as EMWA's Education Officer from 2016 to 2022. She is a member of an NHS Health Research Authority ethics committee.

LWA5b Master Class: Editing English Texts Originating from Non-native Speakers

Profile: This workshop is intended for all medical writers, both native English speakers and those for whom English is a second language, who edit the work of authors who are not native speakers of English. The workshop will be of interest both to those who edit occasionally for colleagues as well as people who edit extensively.

Objective: Editing the work of others is a common component of medical writing. This activity can be especially challenging if the original author was not a native speaker of English and problems of poor writing skills are compounded by lack of fluency in the language. This workshop will give medical writers training and feedback in this sensitive task.

Content: This workshop will take the form of a master class. The workshop leader sees herself primarily as a facilitator and guide in achieving results. That is to say there will be almost no lecture content. Based on examples provided by the workshop leader, participants will work together in small groups to improve a text after which feedback will be provided all together. This workshop demands team work and your active participation. Obviously, therefore, it is necessary that you yourself are a confident speaker of English. Depending on availability it is hoped that other experienced editors will join the class as facilitators. At the end there will be a discussion session on providing feedback to the original author. The emphasis will be on generating texts that communicate clearly rather than reviewing grammar rules.

Rosemary Bischoff

Rosie has been in the pharmaceutical industry since 1974; most of that time as a clinical project leader for a pharmaceutical company in Berlin where she was responsible for the design, conduct and reporting of numerous studies. However, she began her career there writing manuscripts for publication in English and German and ended it as head of clinical operations for the business unit Therapeutics. In 1998 she started her own medical writing business, ClinWrite. She also served on the EMWA Professional Development Committee (EPDC) for many years.

LWA7 Master Class: Semantic Analysis of Medical Writing

Profile: This course should benefit experienced medical writers to enhance their detection, analysis, and revision of semantically distracting sentences. This enhancement will be facilitated by receiving (from the workshop leader) a taxonomic profile of distractions to a submitted sample of original or copyedited medical writing and by receiving oral feedback from the other participants.

Objective: To develop a systematic approach—rather than intuition—for detecting, analyzing, and revising semantic distractions.

Content: By means of a highly interactive workshop format, registrants will gain insight into semantic distractions common to medical writing. Before the workshop, registrants will submit an ~100-word sample of their own vocational writing (or copyediting). They will then receive a taxonomic glossary of typical semantic distractions by which to identify at least one distraction in their submitted writing samples. During the workshop, the workshop leader will review each distraction in the glossary and by the Socratic method ask registrants for a revision option as a test of the distraction validity. Next, the registrants, in pairs, will discuss the semantic distractions in a Master Taxonomic Analysis prepared from Individual Taxonomic Analyses of the submitted writing samples. In addition to the Socratic Method and the paired presentations, the interactive approach is enhanced by limiting the number of registrants to 12.
This workshop is a companion to Syntactic Analysis of Medical Writing.

Michael L Schneir

Michael, a professor in biochemistry, teaches research writing to graduate students and residents. His current research is to determine distractions of clarity in medical writing by focusing on distraction identification at different textual levels (intra- and inter-sentence) and on their syntactic taxonomic classification. The intent is to transform intuitive copyediting into systematic analysis.

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LWA9 Master Class: Syntactic Analysis of Medical Writing

Profile: This course should benefit experienced medical writers to enhance their detection, analysis, and revision of syntactically distracting sentences. This enhancement will be facilitated by receiving (from the workshop leader) a taxonomic profile of distractions to a submitted sample of original or copyedited medical writing and by receiving oral feedback from the other participants.

Objective: To develop a systematic approach—rather than intuition—for detecting, analyzing, and revising syntactic distractions.

Content: By means of a highly interactive workshop format, registrants will gain insight into syntactic distractions common to medical writing. Before the workshop, registrants will submit an ~100-word sample of their own vocational writing (or copyediting). They will then receive a taxonomic glossary of typical syntactic distractions by which to identify at least one distraction in their submitted writing samples. During the workshop, the workshop leader will review each distraction in the glossary and by a Socratic Method ask registrants for a revision option as a test of the distraction validity. Next, the registrants, in pairs, will discuss the syntactic distractions in a Master Taxonomic Analysis prepared from Individual Taxonomic Analyses of the submitted writing samples. In addition to the Socratic Method and the paired presentations, the interactive approach is enhanced by limiting the number of registrants to 12.
This workshop is a companion to Semantic Analysis of Medical Writing.

Michael L Schneir

Michael, a professor in biochemistry, teaches research writing to graduate students and residents. His current research is to determine distractions of clarity in medical writing by focusing on distraction identification at different textual levels (intra- and inter-sentence) and on their syntactic taxonomic classification. The intent is to transform intuitive copyediting into systematic analysis.

LWF13+14 Editing and Proofreading Essentials (Double Workshop)

Note this is a double workshop. You must register for both parts.

Profile: The workshop is intended for medical writers who edit or proofread their own work or that of their colleagues. It is not intended for people who specialise in medical editing. Previous attendance at another workshop is not required.

Objective: This workshop aims to give an overview of editing and proofreading. After completing this workshop, participants should be able to:

- Appreciate how editing and proofreading contribute to document quality
- Identify and correct substantive and technical errors
- Proofread and clearly show changes that need to be made
- Understand how style guides, checklists and other tools can help with editing and proofreading

Content: In this workshop, we will:

- Review the need for both editing and proofreading
- Focus on substantive editing: reorganising and editing to ensure that the correct message is delivered effectively and specifications are met
- Discuss how to work effectively with authors
- Focus on technical editing: getting down to the detail, including checking for format and consistency
- Look at proofreading, to give a 'final polish'
- Consider tools to help the editor.

Barbara Grossman

Barbara Grossman has a passion for proofreading, quality control, and education. She started Hawkeye Medical Limited, a medical writing and consultancy business, after working for a medical publishing company and then a contract research organisation, where she built up and managed its medical writing group. Barbara runs professional development training for companies and educational institutions. She has had many roles in EMWA: workshop leader since 2001, Treasurer 1998–2005, member of the Education Committee 2010–2018, Education Officer 2014–2016. She was awarded an EMWA fellowship in 2005 and is a past EMWA President. In addition, Barbara is an Associate Editor of *Medical Writing*, EMWA's journal.

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LWF15 Using Readability Tools to Help Edit Biomedical Research Articles

Profile: This workshop is for medical writers interested in exploring the use of readability tools to help them produce more readable biomedical research text.

Participants should have some experience of writing and editing scientific research texts, but do not need specialised knowledge.

Objective: This workshop explores 'readability', focusing on how formulas, formula-derived statistics and other tools can help writers edit biomedical research articles. After this workshop, participants should be able to:

- Understand what determines the readability of a document
- Appreciate what readability formulas measure (usually sentence length and word difficulty) and what formula-derived statistics mean
- Recognise the pros/cons and realistic place of readability statistics, particularly when applying them to biomedical research texts
- Use readability statistics and other tools to screen biomedical texts and help improve text readability.

Content: In this workshop, we will:

- Define 'readability' and consider what influences readability
- Consider the importance of readability, particularly of biomedical research articles
- Review commonly-used readability formulas
- Consider the readability of biomedical research articles
- Critically assess the use of readability statistics
- Review other tools available to analyse text and improve readability
- Consider a Readability Screening Checklist.

Practical elements of the workshop will include:

- Comparison of two texts for readability: initial impression and later in-depth comparison using readability statistics and web-based tools
- Analysis of participants' own writing using readability statistics
- Exercises illustrating important determinants of sentence length and therefore readability: the active/passive voice, nominalisation and joining words to improve sentence flow.

John Dixon

John qualified in medicine having studied at Oxford University and Guy's Hospital, London. Initially he trained as a surgeon. After gaining further experience in paediatrics, neonatology, obstetrics and gynaecology, he then became a GP. Since 2003, John has completed an MBA at Warwick University Business School. He then spent five years as Director of Medical Communications at InterComm International Ltd., becoming a healthcare communications consultant and trainer in scientific communications in 2013. His interests include supporting researchers, medical communications agencies and medical equipment companies to ensure their scientific communications are accurate, understandable and use appropriate language. John has provided training for universities and research institutes across Europe in academic writing, presentation delivery, and conference abstract and poster preparation. He is a member of EMWA's Professional Development Committee and also provides a workshop: 'Using readability tools to help edit biomedical

research articles'. He is coauthor of How to Publish in Biomedicine. 500 Tips for Success. 3rd Edition (2016). CRC Press.

LWF21 Effective Medical Writing in English

Profile: This workshop is for both native and non-native speakers of English who would like to write more clearly in English. Participants should have some experience of writing about scientific or medical topics.

Objective: Medical writers worldwide need to convey scientific knowledge in technical documents, peer-reviewed publications or patient communications in clear, concise English in an increasingly time-pressed environment. Yet, many writers lack the skills to write clear, concise English. This workshop will provide specific writing tools and techniques that writers can use to make their texts more precise and easy-to-read. After this workshop, participants will be more confident and better equipped to write more effectively in English.

Content: The first part of this workshop will focus on precise word choice, sentence structure and tenses in medical writing. Participants will learn how to structure a strong sentence in English and specific techniques to self-correct their writing. The second part of the workshop will show how these language elements can be used to tell a story using concise and clearly constructed paragraphs and sections. Using guidelines and templates to facilitate story structures will also be discussed. Participants will be encouraged to participate actively in the workshop and will have the opportunity to practice the techniques learned.

Amy Whereat

Amy is a Consultant Director at *Speak the Speech Consulting*, a micro-network of freelance writers specialised in medical writing and health communication. Previously, she enjoyed a successful career within the pharmaceutical industry in clinical research, medical affairs and marketing at both a local and international level. In these roles, Amy developed a keen interest in scientific storytelling and an extensive knowledge in clinical research in the fields of oncology, gastroenterology, cardiology, and dermatology. In recent years, she has been running medical communication and publication writing courses for medical researchers in France. Amy has been an active member of EMWA since 2011 regularly contributing to 'Medical Writing' on issues that concern medical communication.

LWF4b Medical English – Common Problem Areas for non-native Speakers

Profile: This workshop is primarily intended for medical writers whose native language is not English. Native speakers who encounter difficulties or need to be aware of the difficulties experienced by non-native English writers are also welcome. Participants should be prepared to contribute to group discussions and talk about the content of their pre-workshop assignment.

Objective: Identify, examine and resolve challenges faced by medical writers who are non-native speakers of English, and many native speakers, when producing English-language medical and pharmaceutical texts.

Content: The focus is not on basic English grammar, but on the use of English in the medical and pharmaceutical context. The pre-workshop assignment is designed to stimulate participants to identify problem areas when writing medical and pharmaceutical documents in English. The workshop leaders present and analyse selected topics from the participants' pre-workshop assignments. Exercises performed during the workshop will constitute an interactive forum to discuss these and other problem areas. Participants will then be asked to apply the solutions proposed during the workshop in the post-workshop assignment.

This workshop covers similar topics to the previous workshop 'Medical and Pharmaceutical English for Non-native Speakers' incorporating some new material.

Susanne Geercken

Susanne worked for a small Washington-based magazine in the US, the Translation Department of the United Nations in NY and a Frankfurt bank before she joined Pfizer as a medical translator in 1994. In her role as Manager Translations and Procedures she has been responsible for internal translation, outsourcing, standards and quality control of translation projects. Susanne currently works for the Drug Safety Department within Pfizer Germany. Susanne has also acted as Pfizer in-house trainer for workshops on medical English. To help give future medical translators hands-on-experience in the industry, Susanne established a translation internship program in the Pfizer Karlsruhe Clinical Research Department and served as mentor. She has also given seminars and presentations for the university translation studies program and the Germany Association of Professional Interpreters and translators. Languages are Susanne's passion. She is a trained translator for English and Spanish and also speaks French and Portuguese.

LWF8 Sharpen Up Your Writing Skills

Profile: This workshop will be useful for anyone who wants to make their writing more effective.

Objective: The objective of the course is to help participants write clear, professional text that communicates effectively with their target audience. We will focus on writing for scientific/technical/medical audiences and touch on aspects of writing for patients and the general public. The skills taught are applicable to all types of written communication.

Content: The workshop looks at the principles of effective writing, and how to use them to achieve your communication goals. Topics covered include:

- Structure and style: the do's and dont's of effective writing
- Achieving clarity without 'dumbing down'
- Common style traps in medical and scientific writing
- Writing for patients and the public
- Organising content effectively
- Say it concisely: tips for reducing word count

The course contains interactive class exercises, and learning points are illustrated using real examples of good and bad medical writing.

Jo Whelan

Jo has over 25 years' experience in medical writing, and is currently Value Communication Principal at Visible Analytics Ltd. She specialises in writing for market access, health economics and outcomes research. She has led, managed and written a wide variety of projects for pharmaceutical companies, market access consultancies and medical communications agencies, including health technology assessment submissions, value stories, manuscripts, literature research projects and more. In a previous life she has written numerous news and feature articles for the scientific and consumer health press, and is author of four health-related books for teenagers. She has a particular interest in oncology and holds an MSc in Cancer Therapeutics from Barts Cancer Institute, Queen Mary University of London. Jo served as EMWA Education Officer from 2011 to 2014.

LWF9 Summarising

Profile: This workshop is intended for medical writers who work mostly on regulatory documents. Participants should have a basic knowledge of the most common regulatory documents (e.g. clinical study reports, protocols, and investigator's brochures).

Objective: Medical writers spend most of their time summarising information. The purpose of the workshop is to provide a structured approach to identifying key information so that they can prepare a summary of any regulatory document that meets the needs of the reader and includes appropriate information.

Content: The workshop will start by clarifying what is meant by summarising and the summary documents that we produce. Identifying key messages will be discussed and this will help us to decide what to leave out. Some general guidance

will be given on concise writing and on planning the document. The importance of review and revision will be described and discussed, and we will work on reducing the number of words needed to express a point. Workshop exercises will be used to illustrate the points raised and to give participants the opportunity to practise the methods suggested during the workshop.

Wendy Kingdom

Wendy has more than 30 years' experience of clinical research and medical writing in the pharmaceutical industry. She started her career as a clinical research associate; writing protocols, preparing related study documents, managing studies, and writing clinical study reports. She has been working successfully as a freelance medical writer since 2002 and specialises in clinical and regulatory documents. She has provided commercial and academic training on medical writing. Wendy was EMWA Education Officer 2003–2005, served on the EMWA Professional Development Committee (EPDC) for 5 years, and was Treasurer of EMWA from 2005–2009.

MCA1 Publication Strategy

Profile: This workshop is aimed at writers who are interested in the influence of product marketing on the need for ethical, but product-friendly publications. It is particularly useful for writers who prepare publications that are driven by a publication plan.

Objective: Strategic publication plans are developed in two sections: the publication strategy and the publication plan. The strategy specifically describes how publications can be used to help achieve the marketing objectives of a product by communicating the key product benefits to the right audience at the right time. The aim of this workshop is to introduce the concept of publication strategy and to describe the development of key messages.

Content: The workshop will cover in detail: key message development; selecting the right target audience for publications; considering ideal timelines for message communication through publications, and different strategies. Presentation of the strategy as a comprehensive document will also be discussed.

Julia Donnelly

Julia runs her own medical communication company (Julia Donnelly Solutions Limited) and works predominantly for the pharmaceutical industry. Previously she has worked as a medical writer, project leader, editorial director, technical director and global resource, training and development director in international medical communications. She is an experienced medical writer and trainer, has developed over 40 publication plans and frequently develops the outputs from the plans she manages. Julia served on the EMWA Professional Development Committee (EPDC) 2005-2010 and is a past President (May 2014-2015).

EUROPEAN MEDICAL WRITERS ASSOCIATION

MCA28 Publication Planning

Profile: This workshop is aimed at experienced writers who are interested in or work in publication planning. It is particularly useful for writers who are expected to recommend journals for publications, and congresses for presentations, or are involved in development of scientific communication plans. Participants should know the basics of effective and ethical scientific communication.

Objective: The workshop objective is to convey concepts of strategic communication and publication planning in a unified approach on which to base development and tracking of a publication plan.

Content: Publication plans incorporate details of clinical trials programmes and make recommendations on publications – e.g publication types, journals, meetings and timing to maximise publication opportunity.
The introductory part will refresh the concept of effective communication and the environment of publications. The workshop will cover issues to consider during development of a data-driven plan; e.g. the influence of data availability, journal and meeting choice, and milestone dates. The most relevant aspects of an effective communication strategy and its implementation will be actively discussed.

Andrea Rossi

Andrea Rossi has a degree in biology from Florence University. After a brief spell at the University, he started working in the Italian Affiliate of Eli Lilly as a clinical research associate. In the years that followed he was responsible for statistics, health outcomes, and medical information.
Andrea has been working as a medical writer since 2003. He authored more than 350 disclosures and is acknowledged for his contribution to several others. He has been an EMWA member since 2004 and was on the coordination board of BIAS (Biometristi Italiani Associati) in the period 2007–2009. Andrea has been a trainer for statistics and medical writing in some Italian schools for specialization in medicine and has been a speaker at national and international conferences.
He is an EMWA Ambassador, co-leads EMWA's Scientific Communication SIG (special interest group), and is a workshop leader and past president of EMWA.

MCA3a Systematic Reviews

Profile: The workshop was developed for medical writers with little or no experience in preparing systematic literature reviews of clinical studies. Participants should have a good understanding of study design in clinical research as well as of analysis and presentation of data from clinical studies.

Objective: The objective of the workshop is to give an overview of the purpose of systematic reviews of clinical studies and of the methods and processes used to develop these reviews. After the workshop, participants will be familiar with the

requirements for publication of systematic reviews and will understand how to evaluate the quality of systematic literature reviews of clinical research.

Content:
The workshop will discuss the following topics:

- Purpose of systematic literature reviews of clinical studies
- Definition and characteristics of systematic reviews
- Methods of developing a review
- Writing a publication on a systematic review

Katharina Biester

Katharina initially trained and worked as a paediatric nurse and then studied healthcare management. In 2004, she started working as a researcher in the Department of Non-Drug Interventions at the Institute for Quality and Efficiency in Health Care (IQWiG), Cologne, Germany. In 2010, Katharina switched to IQWiG's Department of Drug Assessment, where she first worked as a senior researcher and then as a Division Head. In 2021, she switched to IQWiG's Department of Health Information, where she is currently working as a researcher. Her main responsibility is the assessment of evidence on the basis of systematic reviews as one of the pillars of evidence-based health information. Since 2016, Katharina has been the Workshop Leader of the EMWA workshop "Systematic Reviews".

MCA4 Manuscript Writing: from Good to Excellent

Profile: Participants should have some experience with writing scientific papers. The workshop is relevant for those who write or edit papers for others, and for those who wish to improve their own papers.

Objective: To increase the likelihood of producing focused – on a clear purpose statement – coherent research papers with well-structured in-depth argumentation.

Content: Participants will learn to create a storyline, to clarify how a study fits into and strengthens the body of knowledge within a field, to distinguish clearly between the introduction and discussion sections, and to develop logical method-centered arguments in the discussion. We will discuss aspects of an example paper – long-term follow-up of breast cancer treatment – and suggested revisions of it, in groups and in plenum. Participants will receive the paper and suggestions before the workshop (as part of the preworkshop assignment). Other topics are the Cs of communication, a 6-step publication-planning-and writing process.

Kari Skinningsrud

Kari is an experienced freelance medical writer who works mainly with medical communication and training, particularly manuscript writing. She has given workshops on manuscript writing at several universities in different countries, gives EMWA workshops on manuscript writing, grant-writing and cross-cultural

communication, and currently serves on EMWA's Professional Development Committee (since 2013). During 2004–09 she was a member of EMWA's Executive Committee. She is bilingual Canadian/Norwegian, has a MSc in biochemistry, has worked for more than 10 years in clinical development in pharmaceutical industry, and is currently a regular writing consultant for a medical device company.

MCA5 Writing for the Public

Profile: This workshop would suit medical writers who have had experience of preparing different types of regulatory documents, and who may be involved in producing documents for patients or other lay audiences. It would also benefit writers involved in medical communications who may be asked to produce written information aimed specifically at non-specialist audiences.

Objective: The workshop aims to explain the challenges posed by low health literacy and numeracy and will explain why this topic is of such importance to the healthcare professions and the pharmaceutical industry. Participants will be given practical examples and shown ways to address these challenges, including how to clarify and improve communication of benefit/risk.

Content: The workshop will outline the difficulties involved in writing for audiences with lower health literacy and numeracy than specialist audiences, and will explain the potential impact this can have on the understanding of concepts such as benefit/risk. The leaders will give examples of how these issues can be addressed, along with general guiding principles. The participants will have the opportunity to practise these in two workshop exercises, one a discussion of their 'translation' of a complex text into a more lay-suitable one (an analysis of their pre-workshop assignments), and the other an outline of what should be included in a Risk Management Plan (RMP) lay summary (to be completed as their post-workshop assignment).

Lisa Chamberlain James

Lisa is a Senior Partner and CEO of Trilogy Writing & Consulting Ltd. Aside from management activities, she leads client projects, with extensive experience in a variety of documents. Lisa has a special interest in writing for the general public and in patient information. Following a PhD and post doc. in Pathology at Cambridge, Lisa began her medical writing career in 2000. Since then she has also been involved in the European Medical Writers Association (EMWA) as a member of the Educational Committee, mentor, leader, and assessor of workshops, and teaches and reviews workshops for the American Medical Writers Association. Lisa holds an EMWA professional development certificate, is a member of TOPRA, DIA, and PIPA, initiated the EMWA PV Special Interest Group, is chair of the Geoff Hall Scholarship Committee, and is a Fellow of the Royal Society of Medicine.

EUROPEAN MEDICAL WRITERS ASSOCIATION

Wendy Kingdom

Wendy has more than 30 years' experience of clinical research and medical writing in the pharmaceutical industry. She started her career as a clinical research associate; writing protocols, preparing related study documents, managing studies, and writing clinical study reports. She has been working successfully as a freelance medical writer since 2002 and specialises in clinical and regulatory documents. She has provided commercial and academic training on medical writing. Wendy was EMWA Education Officer 2003–2005, served on the EMWA Professional Development Committee (EPDC) for 5 years, and was Treasurer of EMWA from 2005–2009.

MCA6a Sponsored Symposia at International Congresses: Expanding into Scientific Project Management and Compliance

Profile: This workshop is intended for writers or editors who already work on different aspects of company-sponsored symposia, such as slide preparation, or those who might wish to get involved with their organisation in the future.

Objective: Company-sponsored symposia (e.g. satellite symposia) are complex events and the medical writer might be involved, not just in developing content or preparing outputs, but also to help co-ordinate the event, secure company clinical, medical and legal review, facilitate slide rehearsals and liaise with the faculty panel. The purpose of this workshop is to consider the separate elements of organising and delivering company-sponsored symposia to introduce the participants to tasks which they might encounter.

Content: The workshop will start at the planning stage and consider all aspects of symposium preparation, including project management, working with logistics agencies and faculty, developing slides following company and country rules, writing proceedings, compliance with EFPIA and Sunshine Act requirements as well as financial reconciliation.

Julia Donnelly

Julia runs her own medical communication company (Julia Donnelly Solutions Limited) and works predominantly for the pharmaceutical industry. Previously she has worked as a medical writer, project leader, editorial director, technical director and global resource, training and development director in international medical communications. She is an experienced medical writer and trainer, has developed over 40 publication plans and frequently develops the outputs from the plans she manages. Julia served on the EMWA Professional Development Committee (EPDC) 2005-2010 and is a past President (May 2014-2015).

EUROPEAN MEDICAL WRITERS ASSOCIATION

Slavka Baronikova

Slavka is a clinical pharmacist with academic scientific and educational experience. After moving to pharmaceutical industry and clinical research over 15 years ago, she followed her passion - scientific disclosure and ethics. As scientific publication lead in GSK Vaccines and later in Shire she was leading scientific publications & disclosure teams in different therapeutic areas and at all stages of drug development. In Takeda, she was responsible for Collaborative Research between company and external institutions and since 2019 is heading scientific publications team in Galapagos NV. Slavka has been an accredited member of EMWA since 2011, EMWA Conference Director since 2014 and a certified ISMPP medical publication professional (CMPP) since 2012.

MCA7 Writing Lay Language Summaries of Study Results according to EU Regulation

Profile: This workshop is for medical writers who want to engage in the writing of lay summaries of study results as mandated by the EU regulation. Participants should already have an understanding of CSR structure (ICH E3) and should know the basics of clinical research (trial design, efficacy and safety analysis, basic statistics).

Objective: Writing lay summaries is a difficult and challenging task. Medical writers with an interest in lay writing are well suited for this new and upcoming activity. However, the provision of lay summaries requires a lot more than good lay language writing. The workshop will introduce the many different aspects of providing lay summaries: the available regulatory guidance, the positions of various stake holders (pharma and patient organisations), the intricacies of the actual writing of lay summaries, and considerations for appropriate distribution of the lay summaries.

Content: The workshop will introduce the requirements for lay language summaries of study results according to the EU regulation. The various guidance documents from stakeholders (TransCelerate, MRCT, European Expert Group) will be introduced and briefly discussed. The content requirements for lay summary will be presented and possible solutions will be presented for discussion. As lay language writing is difficult, only the basic principles of plain language writing will be covered. To learn about the complexity of lay language writing in a confined context, the workshop will have a practical exercise, as participants will be asked to write a short paragraph of a lay summary. In addition, methods for patient involvement into the writing and review of lay summaries will be introduced and the various distribution options for lay summaries as well as the issue of translations will be discussed.

Thomas Schindler

Thomas M Schindler studied biology and linguistics in Germany and the UK, obtained a PhD in molecular physiology, and did postdoctoral research in the UK. Thereafter, he became an editor of popular science books in biology, geography, and astronomy. He then turned to medical writing and has now gained some 25 years of experience in both medical affairs and regulatory medical writing including the preparation of all documents for marketing authorization applications around the globe. He founded and established the medical writing function at Boehringer Ingelheim and has recently headed the Innovation Medical Writing Group focussing on lay communication, good graphics development, video creation and AI-driven writing.
He was a member of the TransCelerate Return of Results work stream, is contributing to the Good Lay Summary Practice initiative and the PFMD Plain Language Summary guidance.

Kamila Sroka-Saidi

Kamila Sroka-Saidi has a PhD in neuro -ciences from the University of Göttingen, Germany. After working as a postdoctoral researcher at Merz Pharmaceuticals, she joined Boehringer Ingelheim Pharma in 2012 and is currently a senior medical writer. She has supported the development of lay summaries as a subject matter expert and has helped establish and maintain interactions with patient organisations on lay summaries.

MCA7a Writing Lay Language Summaries of Study Results according to EU Regulation

Profile: This workshop is for medical writers who want to engage in the writing of lay summaries of study results as mandated by the EU regulation (536/2014). Participants should understand the structure of clinical study reports (ICH E3) and should know the basics of clinical research (trial design, efficacy and safety analysis, basic statistics). Previous experience in writing documents (such as Informed Consent Forms) for study participants or the public is helpful.

Objective: Writing lay summaries is difficult and challenging. Medical writers need to know and apply plain language writing principles. However, the provision of lay summaries comprises many other activities and skills. The workshop will introduce the many different aspects of providing lay summaries: knowledge on the available regulatory guidance, the positions of the various stake holders (pharma and patient organisations), the challenges of the actual writing of lay summaries, and the necessary considerations for appropriate translation and distribution of the lay summaries.

Content: The workshop will introduce the requirements for lay language summaries of study results according to the EU regulation. The various guidance documents

from stakeholders (TransCelerate, MRCT, European Expert Group, Good Lay Summary Practice Initiative [EudraLex 10]) will be introduced and briefly discussed. The content requirements for lay summaries will be presented and possible approaches will be discussed. However, only the basic principles of plain language writing will be covered. Participants will be asked to write a short paragraph of a lay summary based on a clinical document. In addition, methods for patient involvement in writing and review of lay summaries will be highlighted. Furthermore, translation of lay summaries and the various distribution options will be presented and discussed.

Thomas Schindler

Thomas M Schindler studied biology and linguistics in Germany and the UK, obtained a PhD in molecular physiology, and did postdoctoral research in the UK. Thereafter, he became an editor of popular science books in biology, geography, and astronomy. He then turned to medical writing and has now gained some 25 years of experience in both medical affairs and regulatory medical writing including the preparation of all documents for marketing authorization applications around the globe. He founded and established the medical writing function at Boehringer Ingelheim and has recently headed the Innovation Medical Writing Group focussing on lay communication, good graphics development, video creation and AI-driven writing.
He was a member of the TransCelerate Return of Results work stream, is contributing to the Good Lay Summary Practice initiative and the PFMD Plain Language Summary guidance.

Julia A Gindele

Julia A Gindele studied pharmaceutical biology and biological sciences in Germany and obtained a doctoral degree in human biology. She joined Boehringer Ingelheim in 2020 as a Medical Writer and has ever since worked on lay language documents. Recently, she completed a plain language writing degree. She supports the development of lay summaries across all therapeutic areas and regularly writes and reviews lay summaries. In addition, she develops scripts and storyboards for lay summary videos and videos to support trial recruitment. She is involved in the development of further lay language documents such as lay summary comics, lay protocol synopses, and Informed Consent Forms.

MCA8 The Value Story and the Global Value Dossier

Profile: Anyone who wants to learn more about value messages and writing value dossiers, whether they are new to these topics or have some experience with them. The workshop will not assume any prior knowledge of value dossiers or market access, but will assume a basic familiarity with drug development and clinical data.

Objective: After completing the workshop, you should understand the concept of 'value' and be able to construct a value story and value messages for a pharmaceutical product or medical device. You will be familiar with the structure of a typical value dossier and have an understanding of what information is required in each section. You will understand what a value dossier is used for and how to make sure it fulfils users' needs.

Content: Obtaining marketing authorisation is no longer the final step in a drug's journey to market. Manufacturers must also persuade budget-holders (payers) in each country to pay for it. The global value dossier (also known as core value dossier) is a key resource for pharmaceutical company market access teams. The workshop explain the concept of 'value' as it applies to pharmaceutical market access. It will emphasise the importance of the 'value story', and participants will learn how to create evidence-based 'value messages' (i.e. the claims that are used to show the product's clinical, humanistic and economic value). The workshop will then describe the structure of a typical value dossier and guide participants through the information that goes into each section, and where to find it. The emphasis throughout will be on ensuring that the document meets the needs of its end-users.

Jo Whelan

Jo has over 25 years' experience in medical writing, and is currently Value Communication Principal at Visible Analytics Ltd. She specialises in writing for market access, health economics and outcomes research. She has led, managed and written a wide variety of projects for pharmaceutical companies, market access consultancies and medical communications agencies, including health technology assessment submissions, value stories, manuscripts, literature research projects and more. In a previous life she has written numerous news and feature articles for the scientific and consumer health press, and is author of four health-related books for teenagers. She has a particular interest in oncology and holds an MSc in Cancer Therapeutics from Barts Cancer Institute, Queen Mary University of London. Jo served as EMWA Education Officer from 2011 to 2014.

MCA9 Publication Ethics and Compliance

Profile: This workshop is intended for anyone interested in learning about ethical, compliant, and transparent behaviour in the preparation of peer-reviewed scholarly publications. It will focus on Good Publication Practice (GPP) recommendations and guidelines from committees, such as the Committee on Publication Ethics (COPE) and the International Committee of Medical Journal Editors (ICMJE). These are particularly relevant for company-sponsored congress presentations and manuscripts. Participants should have a basic understanding of the publication process, from conception to submission.

Objective: To foster ethical and compliant behaviour in publications, and to enable writers to understand, appreciate, and apply the current industry-wide standards of good publication practices.

Content:

- Summary of the general pharma publication process & importance of transparency
- Review of current guidelines and position statements regarding, amongst others
- Authorship and contributions criteria
- Disclosures and conflicts of interest
- Copyright and intellectual property
- Group discussion on case studies

Sergey Sulima

Sergey obtained a PhD in molecular and cell biology at the University of Maryland (USA) in 2013, and afterwards carried out post-doctoral research in oncology and hematology at the University of Leuven (Belgium) until 2018. His scientific bibliography includes authorship on 16 publications in leading journals such as Cancer Discovery, Leukemia, Nature, and Nucleic Acids Research. Between 2018 and 2022, Sergey was first a scientific and medical writer at BioNTech (Mainz, Germany), and then a scientific writer and publications manager at the Institute for Biological and Medical Imaging at the Helmholtz Center in Munich, Germany. As of January 2022, Sergey is employed as a senior manager in medical communications at Bristol Myers Squibb in Munich, where he is the publications lead for Germany covering the company's clinical pipeline (oncology/hematology, immunology, neurology, and cardiovascular diseases). He is a member of the International Society for Medical Publication Professionals (ISMPP) and holds their Certified Medical Publication Professional (CMPP™) credential. Sergey joined EMWA in 2018, has been a workshop leader since 2020, and became member of the EMWA EPDC in 2023

MCF1a Introduction to Manuscript Writing

Previous title: Writing Successful Manuscripts

Profile: This workshop is intended for medical writers who have little or no experience in writing peer-reviewed manuscripts. No prior experience in manuscript writing is necessary.

Objective: The goal of the workshop is to give medical writers the confidence to begin writing manuscripts and to improve their chances of getting their manuscripts accepted for publication. After completing the workshop, participants should be familiar with the goals, structure, and content of manuscripts destined for peer-reviewed journals; simple steps to take to avoid immediate rejection and improve the chance of getting a manuscript accepted; step-by-step process of writing a manuscript; how to select data to include in a manuscript; and how to handle the peer review process both practically and emotionally.

Content: This workshop will cover:

- Before you start writing a manuscript: choosing a journal
- Instructions and guidelines for manuscripts
- The parts of the manuscript: what belongs where
- Selecting which data to put in a manuscript
- Common pitfalls and how to avoid them
- Step-by-step instructions for putting together a manuscript
- The peer review process and how to learn to love it
- The role of the professional medical writer in manuscript writing

Julia Forjanic Klapproth

Julia Forjanic Klapproth is a poet and scientist who stumbled onto medical writing in 1997. With a PhD in developmental neurobiology and a passion for writing, she enjoys the challenge of grappling with the science while crafting it into easily understandable text. Julia has worn various guises for the good of EMWA over the years including twice being President (2007-2009 and in 2002). In 2002 she co-founded the medical writing company Trilogy Writing & Consulting in Germany and is a Senior Partner. Julia is passionate about medical writing and teaches writers on a broad range of topics.

Phil Leventhal

Phil is a Principal Medical Writer at Evidera, where he specializes in publication writing. He has more than 15 years of experience as a medical writer, has written more than 100 peer-reviewed publications. Phil has been the Editor-in-Chief of Medical Writing and on EMWA's Executive Committee since 2011, and he leads professional workshops and academic workshops on writing peer-reviewed publications throughout Europe and North America.

MCF11 Conference and Meeting Reporting

Profile: Medical writers who either have experience in regulatory writing and wish to explore other aspects of medical writing or have done some conference reporting and wish to improve their skills in this area. Communications writers who have little or no experience of conference reporting.

Objective: The workshop aims to give medical writers the confidence to broaden the scope of the work they can do by covering the practical issues involved in a wide range of reporting projects. The workshop also aims to help the medical writer to improve writing skills and style for this type of writing project.

Content: The workshop will provide participants with practical interactive instruction in writing in several styles: the compelling style used by journalists, the more formal styles used in reporting proceedings, and the commercial styles appropriate for reporting the conclusions of advisory boards and in compiling competitor analyses. This will include discussion on selecting the tone of voice appropriate to the task in hand and the intended audiences. The workshop will also deal with practical and logistic aspects of reporting including:

- News reporting for press releases
- Conference newspapers
- Logistics of expert panel and advisory board reports
- Satellite symposia reports
- Approval processes
- Interviewing key opinion leaders

Lisa Chamberlain James

Lisa is a Senior Partner and CEO of Trilogy Writing & Consulting Ltd. Aside from management activities, she leads client projects, with extensive experience in a variety of documents. Lisa has a special interest in writing for the general public and in patient information. Following a PhD and post doc. in Pathology at Cambridge, Lisa began her medical writing career in 2000. Since then she has also been involved in the European Medical Writers Association (EMWA) as a member of the Educational Committee, mentor, leader, and assessor of workshops, and teaches and reviews workshops for the American Medical Writers Association. Lisa holds an EMWA professional development certificate, is a member of TOPRA, DIA, and PIPA, initiated the EMWA PV Special Interest Group, is chair of the Geoff Hall Scholarship Committee, and is a Fellow of the Royal Society of Medicine.

Nicky French

Nicky started life as a medical information officer with Knoll Pharmaceuticals, before moving to Cambridge to start her writing career with Napp Pharmaceuticals. After four years, Nicky made the move from industry to agency, spending six years with Complete Medical Communications in Glasgow and two years with Adelphi Communications in Bollington. She is currently a freelance medical writer and has worked across a number of therapy areas on a diverse range of projects, including regulatory, marketing, training and educational materials, and publication planning and strategy.

MCF12 Grant Writing

Profile: Researchers who wish to improve the likelihood of getting funds by increasing the quality of their grant applications, and medical writers who would like to assist researchers in writing and improving such applications.

Objective: To increase understanding of grant-provider expectations and priorities, and learn how to translate ideas into strictly defined quantifiable projects.

Content: Competition for research funding is increasing, and well-written grant applications can open or close doors for research careers. An important workshop topic is matching research ideas with funder objectives. Researchers usually write more publications than grant applications; documents with different purposes and target audience. The workshop will focus on similarities and differences between those documents, particularly on topics that journal editors do not request and grant providers emphasize; i.e. expected impact, dissemination plans and the possibility of implementing the described research.

Kari Skinningsrud

Kari is an experienced freelance medical writer who works mainly with medical communication and training, particularly manuscript writing. She has given workshops on manuscript writing at several universities in different countries, gives EMWA workshops on manuscript writing, grant-writing and cross-cultural communication, and currently serves on EMWA's Professional Development Committee (since 2013). During 2004–09 she was a member of EMWA's Executive Committee. She is bilingual Canadian/Norwegian, has a MSc in biochemistry, has worked for more than 10 years in clinical development in pharmaceutical industry, and is currently a regular writing consultant for a medical device company.

MCF12a Grant Writing

Profile: Researchers who wish to improve the likelihood of getting funds by increasing the quality of their grant applications, and medical writers who would like to assist researchers in writing and improving such applications.

Objective: To increase understanding of research funders' expectations and priorities and learn how to translate ideas into strictly defined quantifiable projects.

Content: Competition for research funding is increasing, and well-written grant applications can open or close doors for research careers. Crucial aspects of the workshop are how grant proposals stand out as unique documents and differ from other medical and scientific communication texts. We will introduce funding schemes from the Horizon Europe work program to exemplify different audiences and reviewer expectations. We will discuss differences between top down and bottom-up funding schemes, grant terms and concepts. The workshop will be focused on the unique sections in grant proposals; i.e. expected impact, dissemination plans and implementation of the proposed activities. Finally, we will discuss the grant

evaluation criteria and the most common shortcomings pointed out by evaluation panels.

Kari Skinningsrud

Kari is an experienced freelance medical writer who works mainly with medical communication and training, particularly manuscript writing. She has given workshops on manuscript writing at several universities in different countries, gives EMWA workshops on manuscript writing, grant-writing and cross-cultural communication, and currently serves on EMWA's Professional Development Committee (since 2013). During 2004–09 she was a member of EMWA's Executive Committee. She is bilingual Canadian/Norwegian, has a MSc in biochemistry, has worked for more than 10 years in clinical development in pharmaceutical industry, and is currently a regular writing consultant for a medical device company.

Tamara Bar-Magen Numhauser

Following 15 years of research experience in the fields of molecular virology and physical chemistry Tamara started working as a grant writer in 2015 for academic and research institutions in Finland. Tamara's main goal is to secure new means of research funding. Therefore, she tailors a strategic funding plan for each researcher according to their scientific interests, funding needs, and possibilities, finding suitable funding sources. Currently she also works as a freelancer supporting researchers successfully competing for research funding from European agencies (Horizon 2020 and Horizon Europe), national funding agencies (in Germany, Finland, Spain, Poland, Denmark, Canada, USA, Chile etc.) as well as private foundations.

MCF16 Publication Ethics

Profile: This workshop is intended for all medical and scientific writers who are involved with the preparation of medical publications.

Objective: The purpose of this workshop is to introduce medical and scientific writers to current ethical controversies in biomedical publication and the guidelines that have been developed to help avoid such ethical issues.

Content: The workshop will cover ethical issues that may be encountered when publishing biomedical research. Plagiarism, authorship, ghost writing, prior publication, over- and under-reporting, conflicts of interest and the role of industry, are amongst the topics that will be examined. The guidelines that impact upon medical writing and their practical application will be explored. Participants will discuss recent examples that highlight ethical dilemmas. The two presenters will provide an author and journal perspective.

Julia Donnelly

Julia runs her own medical communication company (Julia Donnelly Solutions Limited) and works predominantly for the pharmaceutical industry. Previously she has worked as a medical writer, project leader, editorial director, technical director and global resource, training and development director in international medical communications. She is an experienced medical writer and trainer, has developed over 40 publication plans and frequently develops the outputs from the plans she manages. Julia served on the EMWA Professional Development Committee (EPDC) 2005-2010 and is a past President (May 2014-2015).

Elise Langdon-Neuner

Elise has a keen interest in biomedical journal policies. She was managing editor for the leading European diabetes journal, Diabetologia, and a new medical journal published by Elsevier, where she established the journal's policies and procedures. Before becoming a freelance editor and publications consultant she worked with researchers at Baxter preparing manuscripts and advising on publication. She is a member of COPE and WAME and the EASE Editorial Board. She regularly publishes articles and gives presentations on publications ethics, wrote the editorial policy chapters in the EASE editor's handbook (2013) and the contributions on English as an additional language to the 4th Edition of 'Medical Writing: a prescription for clarity' (2014). Last but not least she survived 9 years of editing EMWA's journal 'The Write Stuff' (now 'Medical Writing').

MCF17a Using Writing Guidelines

Profile: As professional medical writers should be reporting guideline champions, this workshop is propaedeutic for any workshops on scientific journals or congresses publishing and highly helpful for regulatory writers.

Objective: The growing availability of guidelines and checklists makes identification and use of the most appropriate guidelines for any specific disclosure more difficult. This workshop will help the writer to identify what is available and understand how to choose and use the most appropriate guidelines for their purpose.

Content: The Consolidated Standards of Reporting Trials (CONSORT) statement, issued in 2001, was the first example of a comprehensive and structured guideline on how to communicate the results of randomised clinical trials. In addition, different guidelines, and checklists to use for the results of observational, health outcome, quality of life, mixed-method, and many other types of studies have been published. To complement all of these, pharmaceutical companies have developed Good Publication Practices, individual editors have developed their own guidelines, and most journals have their own instructions for authors. In this workshop, we will

review the main guidelines to identify when and how they can be used by medical writers to improve the productivity and quality of their job.

Andrea Rossi

Andrea Rossi has a degree in biology from Florence University. After a brief spell at the University, he started working in the Italian Affiliate of Eli Lilly as a clinical research associate. In the years that followed he was responsible for statistics, health outcomes, and medical information.
Andrea has been working as a medical writer since 2003. He authored more than 350 disclosures and is acknowledged for his contribution to several others. He has been an EMWA member since 2004 and was on the coordination board of BIAS (Biometristi Italiani Associati) in the period 2007–2009. Andrea has been a trainer for statistics and medical writing in some Italian schools for specialization in medicine and has been a speaker at national and international conferences.
He is an EMWA Ambassador, co-leads EMWA's Scientific Communication SIG (special interest group), and is a workshop leader and past president of EMWA.

MCF18 Abstracts

Profile: This workshop is primarily intended for medical writers who write publications, posters, or conference presentations and who want to improve their abstract writing skills. Medical writers who write summaries that must fit strict format and word limits can also benefit from this workshop. Participants should have some experience writing manuscripts, posters, or conference presentations.

Objective: A well-written abstract allows a reader to quickly understand what an article, poster, or presentation is about, and in many cases, they are the only thing they see. They are also used by journal editors to determine whether to select a manuscript for publication and by conference committees to determine whether a study warrants an oral presentation. Therefore, the abstract needs to capture the reader's interest and transmit the key messages and information, all within strict limitations of length and format. This can pose a significant challenge, even to experienced writers.The objective of this workshop is to learn to identify and condense the key information from a study into the limited number of words and appropriate format for an abstract.

Content: Participants will learn about the purposes of abstracts; key considerations in abstract writing; the different kinds of abstracts and what they should and should not contain; problems in abstracts and how to avoid them; tricks for shortening text; and guidelines for abstracts.

Phil Leventhal

Phil is a Principal Medical Writer at Evidera, where he specializes in publication writing. He has more than 15 years of experience as a medical writer, has written more than 100 peer-reviewed publications. Phil has been the Editor-in-Chief of

Medical Writing and on EMWA's Executive Committee since 2011, and he leads professional workshops and academic workshops on writing peer-reviewed publications throughout Europe and North America.

MCF18a Abstracts

Profile: This workshop is primarily intended for medical writers who write publications, posters, or conference presentations and who want to improve their abstract writing skills. Medical writers who write summaries that must comply with strict format and word limits can also benefit from this workshop. Participants should have some experience writing manuscripts, posters, or conference presentations.

Objective: A well-written abstract allows a reader to quickly understand what an article, poster, or presentation is about, and in many cases, they are the only thing they see. They are also used by journal editors to determine whether to select a manuscript for publication and by conference committees to determine whether a study warrants an oral presentation. Therefore, the abstract needs to capture the reader's interest and transmit the key messages and information, all within strict limitations of length and format. This can pose a significant challenge, even to experienced writers. The objective of this workshop is to learn to identify and condense the key information from a study into the limited number of words and appropriate format for an abstract.

Content: Participants will learn about the purposes of abstracts; key considerations in abstract writing; the different kinds of abstracts and what they should and should not contain; problems in abstracts and how to avoid them; tricks for shortening text; and guidelines for abstracts.

Claire Gudex

Claire is assistant professor in Academic Writing and health service researcher in the area of patient outcome measurement. She has a medical degree and worked for 10 years at the Centre for Health Economics, University of York, UK, before moving to Denmark in 1995, where she has worked at WHO Regional Office, National Institute of Public Health, and the University of Southern Denmark. Claire is a founder member of the EuroQol Group, an international research group for the development of the generic health measure, EQ-5D. She is section editor for the 'Teaching Medical Writing' column in the EMWA journal *Medical writing*.

MCF19 Medical Writing for Vaccines

Profile: This workshop is intended for medical and scientific writers who are interested in developing clinical and peer-reviewed documents in the specific area of vaccines. Pre-attendance at the Introduction to Vaccines workshop (MSF-10) would be beneficial but is not essential.

Objective: At the end of this workshop, scientific/medical writers should be able to:

- Correctly use specific vaccine terminology
- Apply specifics of the vaccine field to clinical documents and peer-reviewed publications

Content: The workshop will start with an exercise to identify vaccine-specific terms from a clinical study synopsis. The terms will be discussed and a glossary presented. The specificities of vaccine writing will be explored. After the break, the target audiences for vaccine publications, with respect to journals and meetings will be discussed and an exercise to develop an outline for an introduction will be undertaken.

Julia Donnelly

Julia runs her own medical communication company (Julia Donnelly Solutions Limited) and works predominantly for the pharmaceutical industry. Previously she has worked as a medical writer, project leader, editorial director, technical director and global resource, training and development director in international medical communications. She is an experienced medical writer and trainer, has developed over 40 publication plans and frequently develops the outputs from the plans she manages. Julia served on the EMWA Professional Development Committee (EPDC) 2005-2010 and is a past President (May 2014-2015).

MCF1a Introduction to Manuscript Writing

Previous title: Writing Successful Manuscripts

Profile: This workshop is intended for medical writers who have little or no experience in writing peer-reviewed manuscripts. No prior experience in manuscript writing is necessary.

Objective: The goal of the workshop is to give medical writers the confidence to begin writing manuscripts and to improve their chances of getting their manuscripts accepted for publication. After completing the workshop, participants should be familiar with the goals, structure, and content of manuscripts destined for peer-reviewed journals; simple steps to take to avoid immediate rejection and improve the chance of getting a manuscript accepted; the step-by-step process of writing a manuscript; how to select data to include in a manuscript; and how to handle the peer review process both practically and emotionally.

Content:

This workshop will cover:

- Before you start writing a manuscript: choosing a journal
- Instructions and guidelines for manuscripts
- The parts of the manuscript: what belongs where
- Selecting which data to put in a manuscript
- Step-by-step instructions for preparing a manuscript
- The peer review process and how to learn to love it
- The role of the professional medical writer in manuscript writing

Julia Forjanic Klapproth

Julia Forjanic Klapproth is a poet and scientist who stumbled onto medical writing in 1997. With a PhD in developmental neurobiology and a passion for writing, she enjoys the challenge of grappling with the science while crafting it into easily understandable text. Julia has worn various guises for the good of EMWA over the years including twice being President (2007-2009 and in 2002). In 2002 she co-founded the medical writing company Trilogy Writing & Consulting in Germany and is a Senior Partner. Julia is passionate about medical writing and teaches writers on a broad range of topics.

MCF21 Promotional Medical Writing: the Dark Side

Profile:

• Medical writers that have worked primarily on the regulatory side with a desire to expand into promotional medical writing

• Medical writers starting out in a healthcare communications and/or advertising Agency

Objective: Hundreds of thousands of words and pages are dedicated to the process of getting pharmaceutical products tested, approved and in the hands of doctors. Near the end of this process, you will find marketers. The people who are working to get these products prescribed for patients. Participants in this workshop will gain understanding about what goes on behind the scenes in pharmaceutical marketing and the role of the medical writer, learn about the wide variety of materials produced at this stage, and be equipped to communicate appropriate effective, consistent selling messages across media.

Content: The objective of the workshop will be achieved by providing participants with an overview of medical communications and where marketing and promotion fits into the bigger picture, going through the basic structure of agencies that work in this field and the role of the medical writer, vering the profile of clients and the end audience, clarifying the difference between pre- and post-launch materials, detailing the types of materials to be created and the regulations that guide pharmaceutical promotions. We will also get into the creative side of things by learning how to craft effective messages that fit into the limitations of what can and cannot be said based on science, ethics and available data. We will conclude by

summarising the keys to becoming a successful medical writer in the field of promotional marketing.

Sarah Chen

Sarah Chen has been working in the pharmaceutical industry for almost 20 years. Starting her career in clinical research in the United States, she made a leap into the world of medical communications and marketing when she moved to Europe 15 years ago. Based in Paris, she has gained experience in several global advertising agencies and is currently working with Publicis Health France. She has helped launch a vast number of pharmaceutical brands over the years on diverse, increasingly digital, platforms. She is an expert on the promotional side of medical communications and medical writing for pharmaceutical marketing. While her main focus is on global and international business, she also interacts with individual, local European markets and their specific challenges, needs and regulations.

MCF22 Developing Effective Oral Presentations

Profile: This workshop is suitable for participants looking to improve their skills in the development of medical communication materials for scientific oral presentations. Previous experience in this area is not required; participants will benefit from this workshop whether they are already working in medical communications and would like to improve their skills, or are looking to move into this area.

Objective: The objective of the workshop is to equip participants with the skills necessary to produce effective oral presentations, whether working on behalf of clients or authors, or looking to improve their own presentations. The workshop will consider the purpose of presentations as a means of communicating scientific findings, and how this can best be achieved through the use of effective data presentation and slide layout, and eye-catching visuals. Best practice and approaches to project management will also be discussed

Content: Through a mixture of lectures, interactive group activities and group discussions, participants will learn:

- Efficient and striking ways of presenting data
- How to prioritise information to avoid over-crowding a presentation
- Practical approaches to managing presentation projects and the development process
- How to gain maximum engagement from presentation attendees, and communicate the key messages

Helen Chambers

Helen is the Global Head of Publications at Costello Medical Consulting, overseeing the publications work delivered by teams across the UK, US and Asia, as well as the

personal and career development of the medical writers themselves. Her focus is on ensuring that projects are delivered to the highest possible quality and that the team are at the forefront of the latest industry developments, such as the development of digital content and patient engagement.
Helen became a Medical Writer in 2013 following a PhD and post-doctoral research in biochemistry at the University of Cambridge, and training as a Clinical Geneticist in an NHS lab. Helen holds the Certified Medical Publication Professional™ (CMPP™) credential from the International Society for Medical Publications Professionals (ISMPP), an Advanced Certificate in Medical Writing from EMWA, and serves as a member of the EMWA Professional Development Committee. She also delivers guest lectures on the University of Cambridge Therapeutic Sciences MPhil course on Medical Communication.

MCF23 Congress Coverage

Profile: Medical writers working in the pharmaceutical, biotech, healthcare or other related industries who would like to know more about the best practices for medical congress coverage. There are no prerequisites for the workshop.

Objective: Some of the most common research deliverables (i.e. abstracts, posters, and slide decks) are presented throughout the year at scientific congresses. Although medical writers can produce these documents, they may also need to attend the congress and develop a congress coverage report. Participants in this workshop will gain an understanding of how to develop key resources before arriving onsite, how to use technology to their advantage at the meeting, and how to capture key messages in their reports.

Content: The workshop will begin with the basics of scientific congresses and consider all aspects of preparation, including pre-congress planning, project management, logistics, and best practices. We will then examine the use of technologies and apps to facilitate gathering information. Finally, the different types/styles of congress reports will be explained.

Jackie Johnson

Jackie is a freelance medical writer and managing director of JLJ Consultancy. She specializes in medical communication deliverables for international pharmaceutical clients and biotech companies. Jackie received an undergraduate degree in Biology from The Ohio State University, completed a PhD in Cancer Biology at The University of South Florida, and did her postdoc at the Netherlands Cancer Center in Amsterdam, Netherlands.

Jackie is also co-founder of The Netherlands SciMed Writers Network (SMWN), a local networking group for science and medical communications professionals in The Netherlands.

EUROPEAN MEDICAL WRITERS ASSOCIATION

MCF29 Introduction to Intellectual Property

Profile: This workshop is intended for medical writers who want to gain a general understanding of what Intellectual Property (IP) is and how it relates to different areas. No previous IP knowledge is required, just a curiosity about copyright, patents etc.

Objective: This standalone introduction to Intellectual Property (IP) introduces the different elements in IP and how they apply in certain situations; how IP laws developed over time; the importance of IP and where to go to access further IP resources.

Content: This workshop introduces IP and the topics of patents, copyright, trademarks, trade secrets, and designs. Examples from the medical world are used for illustration wherever possible.

This is an interactive workshop with a mixture of lecturing, group discussions and exercises. Attendees are requested to have the use of a computer (or internet-enabled phone) during the workshop for some exercises.

Diarmuid De Faoite

Diarmuid is an EMWA workshop leader and served as a member of the EMWA Executive Committee from 2012 to 2022. Originally an academic researcher on the subject of entrepreneurship, he has worked as a business lecturer and researcher, editor and writer in Ireland, Germany and Switzerland. After 15 years in orthopaedic clinical research, he worked for 2 years in communications in the intellectual property rights field. He is now back in medtech, working as the Key Expert Manager for a dental intraoral scanner company. Diarmuid is also a general freelance writer.

MCF2a Developing a Communication Strategy for your Brand

Profile: Medical writers and other professionals working in pharmaceutical, medical devices or communication agency environments who want to know more about the processes involved in developing a communication strategy for a brand.

Objective: For many people, communication strategy is perceived to be a 'dark art'. Although it drives the tactics we implement in our everyday work life, such as manuscripts and symposia, the processes through which the communication strategy for a brand is developed can remain elusive. This workshop will present a stepwise process that can be used to develop an effective and meaningful communication strategy for a brand and then, through interactive mock strategy workshop sessions, show how this process can be implemented in practice.

Content: The objective of this workshop will be achieved by providing participants with an overview of the key elements of strategy development within a framework of a mock strategy workshop. Participants will be taken through the five key steps of strategy development: (1) audience identification and segmentation; (2) market and competitive overview; (3) defining product attributes and positioning; (4) identifying commercial opportunity and critical success factors; and (5) defining communication objectives and themes. The participants will be able to put into practice what they have learnt, taking part in a series of interactive mock strategy workshop sessions to identify unmet clinical needs and target audiences, assess the strengths and weaknesses of Product X, rate and rank differentiating product attributes, and develop a unique positioning for Product X. As part of the pre-workshop assignment, participants will be asked to review some pre-reading on the therapeutic area, so that the benefit of participating in these interactive workshop sessions can be maximised.

Shanida Nataraja

Shanida became a medical writer more than 15 years ago, after completing a PhD and a 2-year postdoctoral research fellowship focusing on the neurophysiology of learning and memory. During this time, Shanida has had the opportunity to work on a wide range of medical communications, marketing, public relations, clinical trial communications and market access activities in numerous therapeutic areas, particularly oncology and cardiology. Currently, Shanida is a Director at AXON Communications, a global healthcare consultancy firm, where she is responsible for, amongst other things, providing scientific, strategic and editorial input into new and existing accounts, as well as leading internal training and an external training, coaching and facilitation offering delivering pragmatic bespoke solutions that help organisations to compete, grow and win business, and cope with change. Shanida has been involved in numerous strategic communication workshops for key pharmaceutical brands, as well as developing strategic communication plans to support clinical trial recruitment and retention, raise awareness of educational initiatives, and enhance internal and external communications with key stakeholders. Shanida has been a member of EMWA since 2001, and between 2006 and 2012, Shanida was EMWA's website manager. As such, she was a member of EMWA's Executive Committee for 6 years, and she is also an experienced workshop leader, having run several workshops during her time with EMWA.

Katrina de Saram

Katrina has over 11 years' experience in healthcare communications, following completion of a PhD focusing on endothelial dysfunction and the role of oxidative stress in type 2 diabetes. During this time, Katrina has delivered a broad variety of projects for global pharmaceutical companies to support the launch and life-cycle management of their products across several therapeutic areas including type 2 diabetes, haemophilia, Alzheimer's disease and oncology (breast cancer). As an

Associate Director at AXON, Katrina acts as technical lead to ensure high-quality editorial content and provides strategic leadership for tailored educational programmes. Katrina brings a wealth of experience in developing strategic communication plans designed to disseminate complex scientific information to a range of target audiences. As part of her role, Katrina provides training on Good Publication Practice as well as pharmaceutical Codes of Practice relating to the evolving compliance landscape.

MCF30 A Structured Approach to Developing Medical Writing Deliverables

Profile: This workshop is intended for medical writers of all levels and specialties. Prior experience as a medical writer is not required; the concepts covered in this workshop can be helpful to even the most experienced medical writers.

Objective: Many medical writers, especially people new to the field, have difficulty coming up with a clear focus for their projects and developing them into a coherent document that accomplishes its objectives. In this workshop, we will provide a structured approach to conceptualizing, progressively building, and managing the development of medical writing deliverables.

Content: Attendees will learn how to formulate a concise concept for their document using the problem statement approach. They will then learn to progressively develop the document from one or more outlines through different full drafts and the final version. The workshop will also cover how to manage the process within a collaborative team to increase efficiency and avoid pitfalls. It will include a combination of lectures, exercises, and discussions

Phil Leventhal

Phil is a Principal Medical Writer at Evidera, where he specializes in publication writing. He has more than 15 years of experience as a medical writer, has written more than 100 peer-reviewed publications. Phil has been the Editor-in-Chief of Medical Writing and on EMWA's Executive Committee since 2011, and he leads professional workshops and academic workshops on writing peer-reviewed publications throughout Europe and North America.

Stephen Gilliver

Stephen (Steve) Gilliver has been an EMWA member for 9 years and is Co-Editor of Medical Writing. He has spent the best part of a decade working as a science editor and more recently a medical writer. Having moved from his native UK to Sweden in 2010, he ultimately settled in Malmö, where he now works home-based. He is a joint British-Swedish citizen and speaks fluent Swedish.

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MCF31 A Structured Approach to Developing Medical Writing Content

Profile: This workshop is intended for medical writers of all levels and specialties. Prior experience as a medical writer is not required. The concepts covered in this workshop can be helpful to even the most experienced medical writers, irrespective of specialty.

Objective: Many medical writers, especially people new to the field, have difficulty coming up with a clear focus for their projects and developing them into a coherent document that accomplishes its objectives. This workshop provides a structured approach to conceptualizing and progressively building the content of any document.

Content: Attendees will choose a document type to work on (e.g., technical report, press release, manuscript, white paper, medical or patient education materials, slide deck). Using materials provided during the pre-workshop assignment, they will learn to formulate a concise concept for their document using the problem statement approach. They will then learn to progressively develop the problem statement into a concept outline, detailed outline, and draft document. This workshop will include a combination of lectures, exercises, and discussions.

Phil Leventhal

Phil is a Principal Medical Writer at Evidera, where he specializes in publication writing. He has more than 15 years of experience as a medical writer, has written more than 100 peer-reviewed publications. Phil has been the Editor-in-Chief of Medical Writing and on EMWA's Executive Committee since 2011, and he leads professional workshops and academic workshops on writing peer-reviewed publications throughout Europe and North America.

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MCF32 How to handle advisory board meetings

Profile: This workshop is aimed at medical writers who are at an initial stage of their career or those who want to learn more about how to handle advisory boards in the most effective way. No prerequisites needed, however this will be an interactive workshop and exchange of experiences with each other.

Objective: The objective of this workshop is to help plan, organize, moderate and report an advisory board. There is not much offer on this subject and there is a growing request from medical writers in consolidating and growing their knowledge on advisory boards.

Content: We will be covering the different stages of an advisory board, from both the perspective of the organizer (usually a pharma client) and its management (usually an events/med comms agency).
From the organizer perspective, we will focus on the needs assessment (why the advisory board is needed, who the audience is, what are the main objectives and desired outcomes).
Then we will share some content about the organization (timelines, invites, preparation of presentations, pre reads for the attendees, the advisory board itself)
And finally, the role of the medical writer: moderation, reporting and delivering a report/executive summary.

Sara Ferrao

Maria Almeida

MCF33 Introduction to Enhanced Content in Publications

Profile: Participants should be broadly familiar with the types of "traditional" publications – abstracts, posters, oral presentations and manuscripts. No previous experience in developing or using enhanced content is necessary.

Objective: This workshop aims to educate attendees on the most commonly utilised forms of enhanced content available to accompany traditional publications (e.g. author interviews, animated summaries, graphical abstracts, plain language summaries) and discuss how these can be incorporated into the project flow.

Content: The workshop will give an overview of the various types of enhanced content that could be developed to accompany a publication, when these might be appropriate and the benefits and drawbacks of each. We will also discuss aspects of project management when developing these materials, common barriers to their uptake and discuss approaches to overcome these.
Please note that this workshop will not teach specialist techniques used to physically develop the materials (e.g. use of any specialist design software).

Helen Chambers

Helen is the Global Head of Publications at Costello Medical Consulting, overseeing the publications work delivered by teams across the UK, US and Asia, as well as the personal and career development of the medical writers themselves. Her focus is on ensuring that projects are delivered to the highest possible quality and that the team are at the forefront of the latest industry developments, such as the development of digital content and patient engagement.

Helen became a Medical Writer in 2013 following a PhD and post-doctoral research in biochemistry at the University of Cambridge, and training as a Clinical Geneticist in an NHS lab. Helen holds the Certified Medical Publication Professional™ (CMPP™) credential from the International Society for Medical Publications Professionals (ISMPP), an Advanced Certificate in Medical Writing from EMWA, and serves as a member of the EMWA Professional Development Committee. She also delivers guest lectures on the University of Cambridge Therapeutic Sciences MPhil course on Medical Communication.

MCF34 The Art of Storytelling through Infographics

Profile: This workshop is designed for anyone in medical writing who wants to improve their skills in visual communication using infographics. No previous knowledge or workshop is required, some experience in design would be helpful but is not essential. All the software will be given during the workshop so there's no need to buy any license as we will work with free tools.

Objective: The ability to communicate scientific and medical topics visually gives any medical writer an advantage and a chance to collaborate on a variety of projects and improve their portfolio. Given the emergence of new technologies, it is important to gain tools that cannot be easily replaced by AI. Infographics and complex displays of information including images are not yet easily achieved by this type of technology, positioning medical writers with visual communication skills in a more competent place.

Content: This workshop will cover the process from the storytelling to the design of the infographic to effectively deliver the message. In the beginning, we will introduce concepts to define the audience and the goal. When the idea and message are clear, we will start with the design of the infographic layout, placing the different elements correctly; in this part, we will introduce design concepts, the idea of repetition, hierarchy, colour, and balance. We will use different free tools for design and illustration. The main goal of this workshop is to understand the process of building an infographic as a layer system. First, the message and the layout, disposition of the different concepts or topics we want to deliver; followed by finding the colours, fonts, and proper illustrations. We will also discuss resolution and different formats (RGB, CMYK) depending on the use of the infographic.

Evguenia Alechine

Evguenia finished her PhD in biochemistry at the University of Buenos Aires, before finding her true passion in science communication. She is now co-editor of the *Medical Writing* journal, chair of the GIMW group, visiting faculty at Bard College (USA) and visibility facilitator in women's leadership at Homeward Bound Projects

(Australia). She is a passionate educator with 15+ years of teaching experience in science and scientific communication, and an EMWA member since 2016.

Sofia Polcownuk

Sofia Polcowñuk has a PhD in Biology from the University of Buenos Aires and is currently a researcher at the University of Glasgow where she discovered her passion for science communication through illustrations. She joined EMWA one year ago and is an active member of the Creative Team. With over 8 years teaching experience in different modalities, Sofia is currently a faculty member at Bard College as part of the Science Communication strand. Sofia is passionate about visual communications and design.

MCF35 Creating Engaging Scientific Posters

Profile: This workshop is suitable for participants of all levels who want to develop more effective posters. Previous experience in this area is not required; participants will benefit from this workshop whether they are already working in medical publications and would like to improve their skills, or are looking to move into this area.

Objective: The objective of the workshop is to guide participants on how to produce engaging scientific posters (and what not to do). The workshop will consider the purpose of posters as a means of communicating scientific findings, and how this can best be achieved through the use of effective data presentation and eye-catching design. Best practices and approaches to project management will also be discussed.

Content: Through a mixture of lectures, interactive group activities, and discussions, participants will learn:

- Tools to create engaging and impactful scientific posters
- How to go from abstract to poster
- How to prioritise information to avoid overcrowding a poster
- Basics of poster design
- Practical approaches to managing poster development projects
- How to gain maximum engagement and communicate the key messages

Evguenia Alechine

Evguenia finished her PhD in biochemistry at the University of Buenos Aires, before finding her true passion in science communication. She is now co-editor of the *Medical Writing* journal, chair of the GIMW group, visiting faculty at Bard College (USA) and visibility facilitator in women's leadership at Homeward Bound Projects

(Australia). She is a passionate educator with 15+ years of teaching experience in science and scientific communication, and an EMWA member since 2016.

Jackie Johnson

Jacqueline (Jackie) L. Johnson, PhD, is a freelance med comms consultant based in Amsterdam. She has 10+ years of scientific writing and med comms experience across most disease states and has worked with top pharma companies both in-house and through global med comms agencies. She is a co-founder of the Netherlands SciMed Writers Network, an EMWA workshop leader (Congress Coverage), and a review editor of Blockchain for Science. She has been an active member of EMWA since 2014.

MCF6 Publication Planning

Profile: This workshop is aimed at writers who are interested in publication planning. It is particularly useful for writers who are asked to make journal and meeting recommendations for manuscripts.

Objective: Strategic publication plans are developed in two sections: the publication strategy and the publication plan. The publication plan takes details of the clinical trials programme and makes recommendations on publications – including publication types, journals and meetings, timing and maximisation of publication opportunity. The aim of this workshop is to introduce the concept of publication planning and to describe the development and tracking of a publication plan.

Content: The introductory part of this workshop will describe the differences between message-driven and data-driven publication plans. Considerations in developing a data-driven plan will be covered in detail including the influence of data availability, journal and meeting choice and milestone dates. A practical session will demonstrate how to prepare a fundamental, chronological plan, and finally, the importance of tracking and maintaining the plan will be discussed.

Julia Donnelly

Julia runs her own medical communication company (Julia Donnelly Solutions Limited) and works predominantly for the pharmaceutical industry. Previously she has worked as a medical writer, project leader, editorial director, technical director and global resource, training and development director in international medical communications. She is an experienced medical writer and trainer, has developed over 40 publication plans and frequently develops the outputs from the plans she manages. Julia served on the EMWA Professional Development Committee (EPDC) 2005-2010 and is a past President (May 2014-2015).

EUROPEAN MEDICAL WRITERS ASSOCIATION

MCF7c Targeting your Audience

Profile: Anyone who wants to develop their fundamental writing skills by building on the philosophy of writing and the writer's role in expressing an idea in many ways. Anyone interested in gaining some practical insight into areas of writing (from public relations to regulatory) they may not encounter on a daily basis.

Objective: The primary goal of writing is to convey information to a target audience. This workshop will explore the fundamental concepts of how a writer can express the same story to vastly varied audiences. The workshop and the post-workshop assignment will introduce, actively explore and exercise the different writing styles commonly used in medical writing, emphasising which style is most effective for each audience, and why. Participants will learn and develop one of the fundamental principles of good writing: recognise who you are writing for and write for them.

Content: The basic philosophy of considering the purpose of a document will be presented and discussed. Real-life examples (good and bad) and hands-on writing with discussion will demonstrate how to use different writing styles in different contexts, from manuscripts to marketing information.

Julia Forjanic Klapproth

Julia Forjanic Klapproth is a poet and scientist who stumbled onto medical writing in 1997. With a PhD in developmental neurobiology and a passion for writing, she enjoys the challenge of grappling with the science while crafting it into easily understandable text. Julia has worn various guises for the good of EMWA over the years including twice being President (2007-2009 and in 2002). In 2002 she co-founded the medical writing company Trilogy Writing & Consulting in Germany and is a Senior Partner. Julia is passionate about medical writing and teaches writers on a broad range of topics.

Lisa Chamberlain James

Lisa is a Senior Partner and CEO of Trilogy Writing & Consulting Ltd. Aside from management activities, she leads client projects, with extensive experience in a variety of documents. Lisa has a special interest in writing for the general public and in patient information. Following a PhD and post doc. in Pathology at Cambridge, Lisa began her medical writing career in 2000. Since then she has also been involved in the European Medical Writers Association (EMWA) as a member of the Educational Committee, mentor, leader, and assessor of workshops, and teaches and reviews workshops for the American Medical Writers Association. Lisa holds an EMWA professional development certificate, is a member of TOPRA, DIA, and PIPA, initiated the EMWA PV Special Interest Group, is chair of the Geoff Hall Scholarship Committee, and is a Fellow of the Royal Society of Medicine.

EUROPEAN MEDICAL WRITERS ASSOCIATION

MCF8a From Clinical Study Report to Manuscript

Profile: Medical writers who write or expect to write manuscripts based on Clinical Study Reports (CSRs). Participants ideally should have already attended the EMWA workshops on 'Writing a Clinical Study Report Using ICH E3' and 'Writing a Manuscript for Publication', or should have equivalent experience in at least one of these areas of medical writing.

Objective: To acquire effective strategies and techniques to write a manuscript for publication based on a CSR.

Content:

· Examine differences between CSRs and manuscripts (pre-workshop assignment)
· Prepare a document checklist for writing a manuscript from a CSR
· Determine which sections of a CSR (ICH E3) are relevant for a manuscript
· Establish guidelines for writing a manuscript based on a CSR
· Determine how to use the tables and figures from a CSR
· Analyse examples of CSR text, figures and tables and convert to manuscript format (post-workshop assignment)

Claire Dyer

Claire is a medical writing manager at Trilogy Writing and Consulting. She worked in pharmaceutical and academic research before and after her PhD in immunology and oncology. Claire has worked within the pharmaceutical and CRO industry in a number of clinical and medical roles including medical information and sales/marketing. After leaving the big smoke in London, she decided on a career in medical writing. Claire has been a medical writer since 2007 and joined the trilogy team in 2013. She has a wide range of experience and a particular interest in regulatory documents covering various therapeutic areas.

MCF8b From Clinical Study Report to Manuscript

Profile: This workshop is aimed at, but not limited to, any medical writer working on manuscripts based on clinical study data. This is a foundation course aimed at gaining a basic understanding of how to effectively develop manuscripts based on trials (RCTs are used as the example throughout) using the CSR as the main data source.

Objective: After completing the workshop, participants will have an understanding of what tools are required to write a manuscript from the data presented in the CSR. They will have discussed source data and where to find it; differences in the presentation of data in a manuscript compared with a CSR; information that should never be left our based on the relevant guidelines (CONSORT will be discussed in more detail) and instructions to authors. They will have also have an understanding

of figures and tables to include and how to choose and change them to be fit for purpose. This workshop does not cover Journal submission activities.

Content:

- Background on manuscripts based on CSRs; who is the audience?
- Background on CSRs and the relevant sections to concentrate on for manuscript writing
- Tools and information you will need to get started (checklist exercise)
- Guidelines (general and CONSORT [as example])
- What to put where (CSR section exercise)
- Thinking about figures and tables (CSR to manuscript exercise)

Julia Forjanic Klapproth

Julia Forjanic Klapproth is a poet and scientist who stumbled onto medical writing in 1997. With a PhD in developmental neurobiology and a passion for writing, she enjoys the challenge of grappling with the science while crafting it into easily understandable text. Julia has worn various guises for the good of EMWA over the years including twice being President (2007-2009 and in 2002). In 2002 she co-founded the medical writing company Trilogy Writing & Consulting in Germany and is a Senior Partner. Julia is passionate about medical writing and teaches writers on a broad range of topics.

MDA2a How to Write a Clinical Evaluation Report

Profile: This workshop is intended for medical writers with regulatory writing experience who are either interested in working with medical devices or who already work with medical devices and are involved in preparing clinical evaluation reports (CERs). Familiarity with the medical device regulation (MDR) 2017/745 and the CER writing guideline MEDDEV 2.7/1 rev. 4 is desirable. Prior attendance at the Introduction to Writing for Medical Devices or From Pharma to Medical Devices workshops would be helpful but is not essential.

Objective: The aim of this workshop is to understand how to write a CER, in particular for higher risk medical devices. Participants will learn how to prepare a CER to MDR standards with reference to the MEDDEV 2.7/1 rev. 4 guideline. Note that conducting a clinical literature review, defining the state of the art and post-market clinical follow-up (PMCF) are only briefly presented in this CER workshop as they are the subject of separate workshops.

Content: Introduction to medical device regulation and market approval process;
Clinical evaluation process;
Clinical evaluation plan;
Clinical evaluation report;
Device under evaluation;
Literature review – current knowledge, state of the art, clinical literature;

Preclinical and clinical data;
Clinical investigations;
Claims
Risk assessment – benefit/risk;
Post-market surveillance (PMS) including PMCF.
The workshop will include group exercises and discussions.

Gillian Pritchard

Gillian Pritchard (Director, Sylexis Limited, UK) is a regulatory medical writer specialising in writing clinical evaluation reports and literature reviews for medical devices. She has worked on medical devices for orthopaedic, cardiology, ophthalmology, gynaecology, wound closure, diabetes and weight loss indications. Gillian trained as a physician and has many years' experience as a research physician in academia and phase I-II contract research; as a clinical project manager of phase III trials with Pfizer GRD; and also with a pharmaceutical and medical devices consultancy. In 2006 Gillian established Sylexis Ltd. to provide regulatory writing services for pharmaceutical and medical device clients. Gillian gives workshops on literature reviews, clinical evaluation reports, drug safety (adverse events and laboratory safety), ICH-GCP and on moving from pharma to medical device writing. She was EMWA Treasurer from 2009 to 2013 and is a member of the Medical Device Special Interest Group (MD SIG).

MDA2b How to Write a Clinical Evaluation Report

Profile: This workshop is intended for medical writers with regulatory writing experience who are either interested in working with medical devices or who already work with medical devices and are involved in preparing clinical evaluation reports (CERs). Familiarity with the medical device regulation (MDR) 2017/745 and the CER writing guideline MEDDEV 2.7/1 rev. 4 is desirable. Prior attendance at the Introduction to Writing for Medical Devices or From Pharma to Medical Devices workshops would be helpful but is not essential.

Objective: The aim of this workshop is to understand how to write a CER, in particular for higher risk medical devices. Participants will learn how to prepare a CER to MDR standards with reference to the MEDDEV 2.7/1 rev. 4 guideline. Note that conducting a clinical literature review, defining the state of the art and post-market clinical follow-up (PMCF) are only briefly presented in this CER workshop as they are the subject of separate workshops.

Content: Introduction to medical device regulation and market approval process;
Clinical evaluation process;
Clinical evaluation plan;
Clinical evaluation report;
Device under evaluation;
Literature review – current knowledge, state of the art, clinical literature;

Preclinical and clinical data;
Clinical investigations;
Claims
Risk assessment – benefit/risk;
Post-market surveillance (PMS) including PMCF.
The workshop will include group exercises and discussions.

Laura C. Collada Ali

Laura C. Collada Ali is a medical writing consultant with more than 20 years of experience in delivering multilingual authoring services for leading pharmaceutical and medical device companies. She regularly prepares CERs, CEPs, SSCPs, PMCF, and related documents for medical devices in the fields of orthopaedics, cardiology, dermatology, and infectious diseases, among others. She also works with pharma companies delivering different kinds of medcomms and regulatory documents.

MDA3 What Medical Writers should know about Medical Device Software

Profile: Participants should have a good understanding of clinical evaluations for medical devices and should have experience in writing clinical evaluation reports. There are no prerequisites, but participants might benefit from obtaining medical device workshops (CEP, CER, SOTA). There is no need for experience with Medical Device Software.

Objective: The workshop will give an introduction into the regulatory framework of Medical Device Software in Europe (MDR 2017/745). Participants will learn about the specific considerations for the clinical evaluation for Medical Device Software.

Content: The workshop will cover the regulatory framework in the European Union for Medical Device Software, classification rules, and specific considerations for the clinical evaluation report and the State of the Art Evaluation. We will take an in-depth look at how to discuss technical performance, valid clinical association, and clinical performance of Medical Device Software in the clinical evaluation. The workshop will be interactive with team exercises and discussions.

Katharina Friedrich

Katharina Friedrich is a medical writing consultant with experience in MDR regulatory writing. She is based in Heidelberg, Germany and works as a Freelance Medical Writing Consultant with focus on orthopedic and cardiovascular devices. She prepares Clinical Evaluation Plans and Reports, PMCF Plans and Reports and SSCPs in compliance with MDR 2017/745 for class I to class III devices. She also supports development projects and the conduction of PMCF activities. As medical doctor she has experience in the field of orthopedic and trauma surgery.

EUROPEAN MEDICAL WRITERS ASSOCIATION

MDF2 Going from Pharma to Medical Devices

Profile: This workshop is primarily intended for medical writers who have some knowledge of regulatory guidance and are interested in working with medical devices. Prior attendance at the Introduction to Writing for Medical Devices workshop would be helpful but is not essential.

Objective: The aim of this workshop is to understand the EU regulatory pathways, to become familiar with the documents used for medical devices to see these in the light of those used for pharma, and to identify transferable skills between pharma and medical devices.

Content:

- Definition of Terms: Pharma vs Medical Devices;
- The EU Regulatory Pathway: Pharma vs Medical Devices;
- Product development steps;
- Regulations and guidelines;
- The Documents: Pharma vs Medical Devices;
- Transferable Skills;
- Case Studies.

Gillian Pritchard

Gillian Pritchard (Director, Sylexis Limited, UK) is a regulatory medical writer specialising in writing clinical evaluation reports and literature reviews for medical devices. She has worked on medical devices for orthopaedic, cardiology, ophthalmology, gynaecology, wound closure, diabetes and weight loss indications. Gillian trained as a physician and has many years' experience as a research physician in academia and phase I-II contract research; as a clinical project manager of phase III trials with Pfizer GRD; and also with a pharmaceutical and medical devices consultancy. In 2006 Gillian established Sylexis Ltd. to provide regulatory writing services for pharmaceutical and medical device clients. Gillian gives workshops on literature reviews, clinical evaluation reports, drug safety (adverse events and laboratory safety), ICH-GCP and on moving from pharma to medical device writing. She was EMWA Treasurer from 2009 to 2013 and is a member of the Medical Device Special Interest Group (MD SIG).

Raquel Billiones

Raquel Billiones has a PhD in Biology and more than 25 years combined experience in scientific and clinical research. She has been a medical writer for >15 years, with core competencies in writing clinical trial and regulatory documents for pharmaceuticals and medical devices. Her experience also includes transparency, disclosure and patient data protection in clinical trial data reporting. Over the years, she took on a wide range of industry positions, as freelancer, employed regulatory writer, and as head of medical writing departments in the CRO and big pharma settings. Raquel is an active member of EMWA, serving in various roles, including

•Medical Writing editorial board member since 2010, currently Editor-in-Chief
•Education Committee member and workshop leader
•Co-founder of the SIGs on Medical Devices and on Sustainability.

MDF2a Going from Pharma to Medical Devices

Profile: This workshop is primarily intended for medical writers who have some knowledge of regulatory guidance and are interested in working with medical devices. Prior attendance at the Introduction to Writing for Medical Devices workshop would be helpful but is not essential.

Objective: The aim of this workshop is to understand the EU regulatory pathways, to become familiar with the documents used for medical devices to see these in the light of those used for pharma, and to identify transferable medical writing skills between pharma and medical devices.

Content: The workshop will compare and contrast Pharma vs Medical Devices with respect to

- definition of terms
- product development steps
- EU regulatory pathways, guidelines and requirements
- documents
- medical writing transferrable skills

Raquel Billiones

Raquel Billiones has a PhD in Biology and more than 25 years combined experience in scientific and clinical research. She has been a medical writer for >15 years, with core competencies in writing clinical trial and regulatory documents for pharmaceuticals and medical devices. Her experience also includes transparency, disclosure and patient data protection in clinical trial data reporting. Over the years, she took on a wide range of industry positions, as freelancer, employed regulatory writer, and as head of medical writing departments in the CRO and big pharma settings. Raquel is an active member of EMWA, serving in various roles, including
•Medical Writing editorial board member since 2010, currently Editor-in-Chief
•Education Committee member and workshop leader
•Co-founder of the SIGs on Medical Devices and on Sustainability.

MDF3 Writing Clinical Investigation Plans for Medical Devices

Profile: This foundation workshop is for those who:

- have never written a clinical investigation plan (CIP, synonym clinical study protocol) for medical devices
- are coming from pharma, or

· already have some experience in writing CIPs and want to gain a more profound understanding of this document.

No attendance at a previous workshop is required. However, participants would benefit from having previously attended 'Basics of Writing for Medical Devices under the MEDDEV rev. 4 and new Medical Devices Regulations' (MDF1).

Objective: The objective of this workshop is to teach participants how to write a CIP for medical devices. Those who have already some experience of writing CIPs will gain a deeper understanding of the background and points to consider.

Content: The workshop will focus on CIPs in Europe.

Step-by-step, chapter-by-chapter participants will be taught how to write a CIP for medical devices. Not only will the different content requirements be explained, but also the strategic impact of specific sections. The workshop will also cover tips and tricks on how to gain specific information.

Beatrix Doerr

Having studied veterinary medicine and written her thesis in parasitology, Beatrix worked first as a veterinary surgeon and then embarked into Clinical Research where she held increasing senior roles. In her last position, Beatrix was heading the European Transcatheter Heart Valve Program being responsible for 5 departments (Pre-and Postmarket Clinical Studies, Department Coordination, Implant Specialists, and Safety). Since 2011, Beatrix is independent with her company Coriuvar which is specialized in cardiovascular devices and predominantly works in regulatory writing, publications and safety reporting.

MDF4 Post-market clinical follow-up for medical devices

Profile: This course is intended for medical writers with little or no experience in regulatory writing, including Post-market Clinical Follow-up (PMCF) Plans and PMCF Evaluation Reports, under the Medical Devices Regulation 2017/745 (EU MDR). There is no prerequisite to attend this workshop but basic knowledge of clinical research and medical device terminologies will be useful.

Objective: With the introduction of the Medical Devices Regulation 2017/745 (EU MDR), each device (or device family) needs a specific PMCF Plan. The results of PMCF activities are summarized in a PMCF Evaluation Report. These documents are subject to predefined review cycles and depend on several other input documents. This course will give you profound insights into the regulatory requirements for PMCF, best practice recommendations on how to prepare PMCF Plans and Reports, and insights into common pitfalls and tips on how to avoid them.

Content: The course includes an introduction to:

- Annex XIV Part B of EU MDR 2017/745 (Post-Market Clinical Follow-up)
- MDCG (Medical Devices Coordination Group) Guidance on PMCF Plans (2020/7)
- The MDCG (Medical Devices Coordination Group) Guidance on PMCF Evaluation Reports (2020/8)
- Input documents and review cycles
- Different methods to conduct PMCF.

You will work with a fictional medical device to think about general and specific PMCF activities. You will also get insights into what triggers PMCF and how to avoid common pitfalls related to PMCF documentation.

Katharina Friedrich

Katharina Friedrich is a medical writing consultant with experience in MDR regulatory writing. She is based in Heidelberg, Germany and works as a Freelance Medical Writing Consultant with focus on orthopedic and cardiovascular devices. She prepares Clinical Evaluation Plans and Reports, PMCF Plans and Reports and SSCPs in compliance with MDR 2017/745 for class I to class III devices. She also supports development projects and the conduction of PMCF activities. As medical doctor she has experience in the field of orthopedic and trauma surgery.

MDF5 Understanding Instructions for Use of Medical Devices and Providing Support in Their Drafting

Profile: This workshop is intended for medical writers with basic or very little knowledge in regulatory writing under either the Medical Devices Directive 93/42/EEC (MDD) or under the Medical Devices Regulation 2017/745 (MDR).

Objective: The Medical Devices Regulation 2017/745 (EU MDR) sets out new requirements for IFUs. For legacy devices, part of the content of the IFUs may come from the Clinical Evaluation of the device, while for new devices it may come from clinical investigation plans conducted before marketing authorization. Medical writers are essential to support manufacturers in writing clear and useful IFUs. These documents are subject to predefined review cycles and depend on several other input documents. This workshop will give you profound insights into the regulatory requirements for IFUs, best practice recommendations on how to draft IFUs, and insights into common pitfalls and tips on how to avoid them.

Content: The course includes the following topics:- Regulatory framework: EU MDR 2017/745 requirements and definitions- Content and structure of the Instructions for Use- Where do all those contents come from? Legacy devices vs new devices- Recommendations for the writing process: Tips to improve writing of the IFUs- Usability and readability- Images, photos and symbols- Where else and how the content of IFUs is used.We will navigate through many examples about content, writing and possible pitfalls. You will get

insights on how to improve the quality of IFUs and contribute to the drafting process.

Laura C. Collada Ali

Laura C. Collada Ali is a medical writing consultant with more than 20 years of experience in delivering multilingual authoring services for leading pharmaceutical and medical device companies. She regularly prepares CERs, CEPs, SSCPs, PMCF, and related documents for medical devices in the fields of orthopaedics, cardiology, dermatology, and infectious diseases, among others. She also works with pharma companies delivering different kinds of medcomms and regulatory documents.

Katharina Friedrich

Katharina Friedrich is a medical writing consultant with experience in MDR regulatory writing. She is based in Heidelberg, Germany and works as a Freelance Medical Writing Consultant with focus on orthopedic and cardiovascular devices. She prepares Clinical Evaluation Plans and Reports, PMCF Plans and Reports and SSCPs in compliance with MDR 2017/745 for class I to class III devices. She also supports development projects and the conduction of PMCF activities. As medical doctor she has experience in the field of orthopedic and trauma surgery.

MDF6 Safety Reporting for Medical Devices Part 1

Profile: This workshop is for everybody who wishes to embark on safety reporting/ writing for medical devices as well as those that want to learn more about the specifics of safety reporting to gain a better understanding about processes, regulations and definitions (e.g. about the differences between adverse events and device deficiencies). No previous experience is required.

Objective: Safety reporting for medical devices is an emerging field that can utilize the skills of medical writers and several companies have started to hire medical writers for that purpose. In addition, the knowledge gained in this workshop will deepen the insights of adverse events that may also be beneficial in writing documents such as clinical investigation plans.

Content: Part 1 (of 2) provides a general introduction to safety writing including key areas medical writers may be involved in, definitions, relevant regulations and guidelines, IMDRF coding, and safety reporting including the Clinical Investigation Summary Report Form, and individual and summary reports.
The second part will touch base on topics such as literature review for trending, patient narratives, safety plan and coding, clinical events committee and data safety monitoring board guidelines, risk management documents, post-market surveillance plans, PSURs, SSCPs, and the safety part of informed consent forms, clinical investigation plans and instructions for use.

EUROPEAN MEDICAL WRITERS ASSOCIATION

Beatrix Doerr

Having studied veterinary medicine and written her thesis in parasitology, Beatrix worked first as a veterinary surgeon and then embarked into Clinical Research where she held increasing senior roles. In her last position, Beatrix was heading the European Transcatheter Heart Valve Program being responsible for 5 departments (Pre-and Postmarket Clinical Studies, Department Coordination, Implant Specialists, and Safety). Since 2011, Beatrix is independent with her company Coriuvar which is specialized in cardiovascular devices and predominantly works in regulatory writing, publications and safety reporting.

MDF7 How to Compile the Summary of Safety and Clinical Performance (SSCP) for Medical Devices

Profile: This workshop is intended for participants wishing to learn about the requirements, the content and structure, input documents, and review cycles of the Summary of Safety and Clinical Performance (SSCP) for medical device. Basic knowledge of the Medical Devices Regulation 2017/745 is required.

Objective: The Medical Devices Regulation 2017/745 (EU MDR) introduced a new document – the Summary of Safety and Clinical Performance (SSCP) – to provide access to safety and performance data to the public. Medical writers are essential to support manufacturers in writing structured and clear SSCPs for both healthcare professionals and lay persons. The SSCP requires input from several parts of the technical documentation and is subject to predefined review cycles. This workshop will give you profound insights into the regulatory requirements for the SSPCs, best practice recommendations on how to draft your first SSCPs, as well as tips and tricks on writing for a lay audience.

Content: The course includes the following topics:

- Regulatory framework: Article 32 of the EU MDR 2017/745
- Structure and Content - The MDCG (Medical Devices Coordination Group) Guidance on SSCPs (2019-9)
- Input documents and review cycles
- How to summarize safety and performance data for the SSCP
- Differences between the healthcare professional and lay person section

The workshop will include exercises, group discussions, and best practice tips.

Katharina Friedrich

Katharina Friedrich is a medical writing consultant with experience in MDR regulatory writing. She is based in Heidelberg, Germany and works as a Freelance Medical Writing Consultant with focus on orthopedic and cardiovascular devices. She prepares Clinical Evaluation Plans and Reports, PMCF Plans and Reports and SSCPs in compliance with MDR 2017/745 for class I to class III devices. She also supports

development projects and the conduction of PMCF activities. As medical doctor she has experience in the field of orthopedic and trauma surgery.

MDF8 Writing a Clinical Evaluation Plan for Medical Devices

Profile: This workshop is intended for medical writers with little or no experience in regulatory writing under the Medical Devices Regulation 2017/745 (EU MDR) who would like to learn how to prepare a compliant Clinical Evaluation Plan. There is no prerequisite to attend this workshop, but basic knowledge of clinical research methodology and medical device terminologies will be useful.

Objective: The Clinical Evaluation Plan (CEP) is a key document that provides the foundation on which the clinical evaluation of a medical device is based. The objective of this workshop is to introduce participants to the regulatory requirements for this document and provide them with an understanding of how a well-written CEP can streamline the clinical evaluation process.

Content: The workshop will provide a detailed overview of the contents of the CEP required under EU MDR. Specific topics covered include determining the clinical evaluation strategy best suited to your medical device, special considerations for legacy devices and new development, identifying appropriate safety and performance measures, identifying suitable equivalent or benchmark devices, the Clinical Development Plan, and an initial assessment of PMCF needs. The workshop will include group exercises and examples for low, medium, and high-risk class devices.

Kelly Goodwin Burri

Kelly joined Stryker as a Senior Clinical Evaluation Specialist in 2018 and recently transitioned to the role of Manager Real-World Data Science. She has almost 20 years of professional experience in medical writing, clinical research, and epidemiology. She has worked in various medical writing roles in the pharmaceutical industry, as a project manager of large multi-national clinical trials and cohort studies, and as an epidemiologist and project leader for patient registries in the fields of spine surgery and pelvic trauma. Kelly has authored or co-authored several peer-reviewed publications in the fields of biomechanics, surgical outcomes, and infectious diseases. She has dual Master of Science degrees in Epidemiology and Biomechanics and an undergraduate degree in Engineering Science. Having first joined EMWA in 2003, Kelly currently serves as the chair of the Medical Devices Special Interest Group.

Samuel Hoare

Samuel Hoare is a Senior Clinical Evaluation Specialist with more than 6 years of experience working in the medical device industry. His professional experience

includes medical writing in the context of clinical evaluations of orthopaedic devices, management of Notified Body (NB) interactions within various regulatory frameworks, and defence of processes and documentation in context of NB audits. Prior to his current role, Samuel worked in the area of bone morphology analysis through use of 3D modelling and analytical technologies. He has authored and co-authored peer-reviewed publications and conference posters in the field of orthopaedics and traumatology. He has a Master of Arts in Biological Anthropology, a Post-Graduate Honours degree in Biological Anthropology, and a double-major Bachelor of Arts in Anthropology and Ancient History. Samuel has been a member of EMWA since 2020 and is an active member of the Medical Device Special Interest Group.

MDF9 Writing the State for the Art of medical devices according to the EU Medical Devices Regulation

Profile: This course is intended for medical writers with little experience in regulatory writing.
We will assume that participants have basic knowledge of the directives and regulations governing medical devices, such as the MDD and MDR. (Reading about these regulations will be part of the pre-workshop assignment.)

Content: The State of the Art has become the strategic kick-off of any medical device evaluation. It includes information about the medical background, clinical conditions, and alternative therapies related to a medical device. In addition, the State of the Art section needs to identify benchmark devices, which are the foundation to define parameters for safety and performance, the risk-benefit profile, and respective acceptance criteria. Separate systematic literature searches are required to identify relevant background information and benchmark devices. Although the term "State of the Art" is mentioned several time in the EU Medical Devices Regulation 2017/745, and Notified Bodies pay special attention to this issue, there is a lack of clear definitions.

Understanding the relevant parts of a State of the Art section and knowing where to start can be challenging, especially when writing your first Clinical Evaluation Reports.
Also, as a medical writer, you may face devices with little background information for which the literature search can become a challenge.
Finally, the State of the Art section is subject to regular updates and will also be included in other documents, such as the Summary of Safety and Clinical Performance (SSCP).
This workshop will give you profound insights into the regulatory requirements for the State of the Art, best practice recommendations on how to structure your search, and how to identify your benchmark devices and parameters.

- Regulatory framework: EU MDR 2017/745 requirements and definitions

- Content and structure of the State of the Art
- Systematic literature searches for the State of the Art
- Benchmark devices and benchmark parameters for safety and performance
- How to compare the State of the Art information to the subject device
- Review cycles and updates

Laura C. Collada Ali

Laura C. Collada Ali is a medical writing consultant with more than 20 years of experience in delivering multilingual authoring services for leading pharmaceutical and medical device companies. She regularly prepares CERs, CEPs, SSCPs, PMCF, and related documents for medical devices in the fields of orthopaedics, cardiology, dermatology, and infectious diseases, among others. She also works with pharma companies delivering different kinds of medcomms and regulatory documents.

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MSA1 Advanced Epidemiology

Profile: Experienced writers with basic knowledge of incidence, prevalence, relative measures of association and descriptive statistics. *Participants are recommended to take the "Basics of Epidemiology for Medical Communicators" workshop before enrolling in this advanced workshop.*

Objective: The underlying principle of this workshop is that medical communicators have a key gatekeeper's role in ensuring accurate writing and interpretation of medical findings. Participants will be provided with data interpretation insights according to epidemiological concepts. Focus is on the "critical" appraisal of reported medical findings and the application of epidemiological tenets to improve their writing. Common research designs, relative measures of association, and causality development will be discussed using recent examples from clinical medicine, public health and pharmacoepidemiology. Selected reporting guidelines are explained as useful tools to support critical writing. Class format will combine lectures with interactive group exercises and fun quizzes. No calculations, tabulations or graphing are required for this workshop.

Main objectives are:
• to provide data interpretation insights based on "critical" epidemiological principles

• to encourage the use of reporting guidelines and checklists (including STROBE, CONSORT)

Content:

- brief overview of common research designs - strengths and limitations
- association and causation - making sense of a confounding couple
- use of reporting guidelines to enhance medical writing and interpretation

Rita Wellens

Rita has 20-years-plus experience in program and project management (Phase I-IV) across multiple therapeutic fields, medical writing, and training for main pharma and global CROs. She managed epidemiology projects worldwide for GSK Biologicals and specialised in pharmacoepidemiology and pharmacosurveillance at the London School of Hygiene and Tropical Medicine. She held university faculty positions mainly in the USA with focus on human biology, epidemiology, biostatistics, and research methodology. She was a Fulbright scholar and recipient of several NIH and AHA research grants. She took part in the EMWA Professional Development Committee (2007 - 2010), and served as EMWA Vice-President (2010 - 2011) and President (2011- 2012). Her involvement as an EMWA workshop leader started in 2001. She is now active as a consultant in clinical research and epidemiology. Rita enjoys being a teacher and mentor for project managers and medical writers. She strongly feels that medical communicators play a crucial role in the critical appraisal and sound reporting of medical findings.

MSF1 Pharmacology for Medical Writers: the Basics

Profile: You will normally either have:

- Had no formal instruction in pharmacology
- Undertaken formal instruction in pharmacology in the past but wish to update your knowledge

Objective: Although some types of medical writing need little or no knowledge of pharmacology, for many types it is essential. Key elements of pharmacology include:

- The mechanisms of action of drugs
- Analysing and describing the properties of drugs in qualitative and quantitative terms
- The origins of adverse effects

After the workshop you will understand:

- The main ways in which drugs produce their effects
- The use of internationally agreed terminology for the qualitative and quantitative properties of drugs.

Content: The workshop will be largely didactic but participants will be expected to contribute during the workshop. You will also be encouraged to discuss any problems or difficulties you have with pharmacology and its terminology.

John Carpenter

John, a pharmacologist, was a lecturer in pharmacology at Manchester University from 1974 to 1992, where he studied drugs and the movement of ova through oviducts, anti-asthma drug models, and the pharmacokinetics of alcohol (never a shortage of volunteers). He has written or contributed to several pharmacology textbooks, and acted as an expert witness in court cases involving alcohol. In 1992, he became a full-time medical writer, initially with Gardiner-Caldwell Communications, then as Medical Team Director at Medical Action Communications and briefly as Medical Director at OCC. Since 2001, he has been a freelance medical writer, medical communications consultant, and trainer. John is a regular contributor to the range of training courses offered by the Proper Medical Writing Group in Poland and by Kemic Bioresearch in Canada. Satisfied customers include the Canadian Government's medicines regulatory department. He has served on the EMWA Executive Committee as Universities Liaison Officer and was a member of the EMWA Professional Development Committee (EPDC) from 2005 to 2010.

MSF10 An Introduction to Vaccines

Profile: This workshop is intended for anyone who is interested in learning more about vaccines.

Objective: At the end of this workshop, scientific/medical writers should be able to

- Understand how vaccines are developed and used
- Have a good understanding of current issues in vaccinology

Content: The workshop will start with a general introduction to vaccines (basics of immunology, types of vaccines, use of adjuvats), followed by a discussion of methods of administration, scheduling and testing. Recent issues/developments will also be explored.

Note that the format will be lecture-based with some quizzes and brief exercises.

Luise Kalbe

Luise Kalbe has two Masters and a PhD in biochemistry and speaks six languages. She has work experience in academic research and the industry in different disease and vaccine areas, at the European Commission, and as a mathematics and science teacher. Currently working at GSK in publication management, she has led several workshops and trainings in publication writing at GSK over the past years and a workshop at EMWA in 2014.

Julia Donnelly

Julia runs her own medical communication company (Julia Donnelly Solutions Limited) and works predominantly for the pharmaceutical industry. Previously she has worked as a medical writer, project leader, editorial director, technical director

and global resource, training and development director in international medical communications. She is an experienced medical writer and trainer, has developed over 40 publication plans and frequently develops the outputs from the plans she manages. Julia served on the EMWA Professional Development Committee (EPDC) 2005-2010 and is a past President (May 2014-2015).

MSF10a An Introduction to Vaccines

Profile: This workshop is intended for anyone interested in learning about vaccines, particularly scientific/medical writers with little or no background on the topic, but also those interested in refreshing or updating their knowledge. Participants should have a basic understanding of molecular biology (DNA RNA protein).

Objective: To enable writers to understand and appreciate the basic principles of vaccinology, and how these principles are applied in vaccine development.

Content: The workshop will cover the following topics:

- Basics of immunology
- History of vaccines
- Types of vaccines and their production, administration, mode of action, and known/potential issues
- Recent developments such as COVID19 vaccination, mRNA vaccines, and vaccines against cancer

Sergey Sulima

Sergey obtained a PhD in molecular and cell biology at the University of Maryland (USA) in 2013, and afterwards carried out post-doctoral research in oncology and hematology at the University of Leuven (Belgium) until 2018. His scientific bibliography includes authorship on 16 publications in leading journals such as Cancer Discovery, Leukemia, Nature, and Nucleic Acids Research. Between 2018 and 2022, Sergey was first a scientific and medical writer at BioNTech (Mainz, Germany), and then a scientific writer and publications manager at the Institute for Biological and Medical Imaging at the Helmholtz Center in Munich, Germany. As of January 2022, Sergey is employed as a senior manager in medical communications at Bristol Myers Squibb in Munich, where he is the publications lead for Germany covering the company's clinical pipeline (oncology/hematology, immunology, neurology, and cardiovascular diseases). He is a member of the International Society for Medical Publication Professionals (ISMPP) and holds their Certified Medical Publication Professional (CMPP™) credential. Sergey joined EMWA in 2018, has been a workshop leader since 2020, and became member of the EMWA EPDC in 2023

MSF12 Antibiotic Development: A Guide for Writers

Profile: Writers with little or no experience of the clinical development of antibiotics.

Objective: A jargon-busting introduction to bacterial infections and the development of new antibiotics that gives the writer confidence when discussing and writing about breakpoints, susceptibility, ECOFFs, wild types, acquired resistance and much more.

Content: Infection and the development of antibiotics is a particularly difficult area that is associated with a unique terminology. This interactive workshop aims to demystify some of the daunting complexities that medical writers will encounter when starting out in this fascinating field. As background, the workshop will cover nomenclature and classifications, the incidence of common bacterial diseases, modes of action for common drug classes and the main mechanisms of bacterial resistance. After covering these basics, attendees will explore the practicalities of measuring resistance and then look at the key considerations for study design, conduct and reporting. Throughout, the emphasis will be on equipping the medical writer with the knowledge needed to understand and contribute meaningfully to the development of clinical development documents.

Andrew Walker

Andrew has spent over 20 years working in clinical development. As a medical writer, he has worked as a freelance writer, for agencies and in-house for AstraZeneca. Andrew has worked in medical communications as well as a regulatory writer, the latter being his real area of expertise on account of the 15 years spent in the regulatory writing group at AstraZeneca. During this time, he was involved in the design and delivery of many regulatory submissions, mentoring and training of staff, and the development of many of the processes for delivering high-quality regulatory documents. In addition to writing, Andrew also spent several years as an Information Director with responsibilities for design and interpretation of clinical programs, notably in the infection therapy area. Since leaving AstraZeneca, he has joined Bioscript Regulatory and continues to work in the infection area providing expertise and support to clients who are developing novel antibiotics.

MSF13 Cell Signalling and its Importance for Drug Development

Profile: Any regulatory medical writer looking to understand the basics of cell signalling and how it can be used for modern drug development.
Ideally, participants will have taken workshops MSF9 (The Fundamentals of Genetics for Medical Writers) and MSF1 (Pharmacology for Medical Writers: the Basics) or have an equivalent knowledge, but the basic concepts required are included in the pre-workshop assignment as a reminder.

Objective: As medical writers, some knowledge of molecular biology (including cell signalling) is important in order to understand the molecular mechanism of action of a drug, which is the fundament for many clinical development programs.

The aim of this workshop is to introduce basic concepts of signal transduction, how this knowledge can be used to develop new drugs, and how details about cellular signalling are described in regulatory documents and manuscripts.

Content: The basic theoretical concepts of cellular signalling will be introduced (forms of signalling, common signalling molecules, components of signalling cascades, etc). How the knowledge of these basic concepts can help drug development will be discussed. The molecular mechanism of action of several marketed drugs will be introduced and compared to the descriptions found in relevant regulatory documents (examples from the EMA database) and manuscripts.

Laia Pedro-Roig

Laia Pedro-Roig has a Degree in Chemistry from the *Universitat d'Alacant* and a PhD in Biochemistry and Molecular Biology carried out at the *Universitat d'Alacant*, University of Florida, and *Goethe Universität* (Frankfurt, Germany). Following her PhD, she moved to a post-doctoral position at the Medical Research Council (UK). Overall, Laia has 10 years of research experience in cell signalling, including preclinical drug development in the Parkinson's disease area. She is currently a medical writer at Trilogy Writing & Consulting.

MSF14 Introduction to Virology

Profile: This workshop is intended for scientific/medical writers with little or no background in virology, or those interested in refreshing or updating their knowledge on the fundamentals of the subject. It is particularly relevant for writers working in such areas as infectious diseases, vaccines, and immunology. Participants should already have a basic understanding of molecular biology (DNA - RNA - protein).

Objective: To enable writers to understand and appreciate the basic principles of virology, and how these principles are applied in the medical sciences

Content: The workshop will cover the following topics:

- Brief history of virology
- Relevant virology terminology
- Structure and function of viruses
- Viral diseases and their prevention and control
- Emerging topics: Corona vaccines and therapeutic applications of virology

Sergey Sulima

Sergey obtained a PhD in molecular and cell biology at the University of Maryland (USA) in 2013, and afterwards carried out post-doctoral research in oncology and hematology at the University of Leuven (Belgium) until 2018. His scientific bibliography includes authorship on 16 publications in leading journals such as Cancer Discovery, Leukemia, Nature, and Nucleic Acids Research. Between 2018 and 2022, Sergey was first a scientific and medical writer at BioNTech (Mainz, Germany),

and then a scientific writer and publications manager at the Institute for Biological and Medical Imaging at the Helmholtz Center in Munich, Germany. As of January 2022, Sergey is employed as a senior manager in medical communications at Bristol Myers Squibb in Munich, where he is the publications lead for Germany covering the company's clinical pipeline (oncology/hematology, immunology, neurology, and cardiovascular diseases). He is a member of the International Society for Medical Publication Professionals (ISMPP) and holds their Certified Medical Publication Professional (CMPP™) credential. Sergey joined EMWA in 2018, has been a workshop leader since 2020, and became member of the EMWA EPDC in 2023

MSF2 Pharmacology for Medical Writers: Part 2 – Drugs Acting on Peripheral Body Systems: Hormones, Inflammation, Gastrointestinal System

Profile: You will normally either have:

- Had no formal instruction in pharmacology.
- Undertaken formal instruction in pharmacology in the past but wish to update your knowledge.

Note: if you have no knowledge of pharmacology, you should not take this workshop until you have taken the workshop 'Pharmacology for Medical Writers, Part 1: The Basics'.

Objective: This workshop is intended to supplement knowledge and skills acquired in the workshop 'Pharmacology for Medical Writers, Part 1: The Basics'. After the workshop participants will understand the properties of the several groups of drugs, their mechanisms of action, how they produce adverse effects, what they are useful for, and how they are used in practice.

Content: The workshop will be largely didactic, although participants will be expected to interact with the presenter during the workshop. It will comprise both formal descriptions and exercises. You will also be encouraged to discuss any problems or difficulties you have with the pharmacology of these groups of drugs.

John Carpenter

John, a pharmacologist, was a lecturer in pharmacology at Manchester University from 1974 to 1992, where he studied drugs and the movement of ova through oviducts, anti-asthma drug models, and the pharmacokinetics of alcohol (never a shortage of volunteers). He has written or contributed to several pharmacology textbooks, and acted as an expert witness in court cases involving alcohol. In 1992, he became a full-time medical writer, initially with Gardiner-Caldwell Communications, then as Medical Team Director at Medical Action Communications and briefly as Medical Director at OCC. Since 2001, he has been a freelance medical

writer, medical communications consultant, and trainer. John is a regular contributor to the range of training courses offered by the Proper Medical Writing Group in Poland and by Kemic Bioresearch in Canada. Satisfied customers include the Canadian Government's medicines regulatory department. He has served on the EMWA Executive Committee as Universities Liaison Officer and was a member of the EMWA Professional Development Committee (EPDC) from 2005 to 2010.

MSF3 Basics of Epidemiology for Medical Communicators

Profile: Medical writers with basic knowledge of descriptive statistics who want to gain insight into the usefulness of epidemiological principles for medical writing.

Objective: This workshop is designed for medical writers with little to no experience with epidemiology and its applications in the pharmaceutical business and public health. Participants will be provided with a general overview of relevant applications of epidemiology for medical writers. The scope and relevance of contemporary epidemiology for medical writers will be discussed using examples from clinical medicine, public health and pharmacoepidemiology. In addition, commonly used measures of disease occurrence – incidence and prevalence - and their use in research designs will be reviewed. The class format combines lectures with group exercises.

The main objectives are:

- Provide an overview of the applications of epidemiology in the business of medical writing
- Explain the use, significance and pitfalls of commonly used disease frequency indicators: prevalence and incidence

Content: Three major topics will be covered:

- Scope of contemporary epidemiology for medical writers
- Relevance of contemporary epidemiology for medical writers
- Basic measures of epidemiology for medical writers: prevalence and incidence

Rita Wellens

Rita has 20-years-plus experience in program and project management (Phase I-IV) across multiple therapeutic fields, medical writing, and training for main pharma and global CROs. She managed epidemiology projects worldwide for GSK Biologicals and specialised in pharmacoepidemiology and pharmacosurveillance at the London School of Hygiene and Tropical Medicine. She held university faculty positions mainly in the USA with focus on human biology, epidemiology, biostatistics, and research methodology. She was a Fulbright scholar and recipient of several NIH and AHA research grants. She took part in the EMWA Professional Development Committee (2007 - 2010), and served as EMWA Vice-President (2010 - 2011) and President (2011- 2012). Her involvement as an EMWA workshop leader started in 2001. She is now active as a consultant in clinical research and epidemiology. Rita enjoys being a

teacher and mentor for project managers and medical writers. She strongly feels that medical communicators play a crucial role in the critical appraisal and sound reporting of medical findings.

MSF4a Pharmacogenomics

Profile: This workshop is aimed at medical writers with little or no understanding of the basics of pharmacogenomics and its applications in drug development, and those who may be working on projects that include pharmacogenomic substudies. A basic knowledge of genetics is essential, however, the three main principles of genetic theory (replication, transcription and translation) will be reviewed.

Objective: The objective of this workshop is to provide participants with an understanding of how drug response is affected by inherited differences, and how this knowledge is applied to drug development. Implications to medical writers (including issues such as ethics and regulations) will be addressed.

Content: Participants will learn the basics about pharmacogenomic studies and their impact on drug development, and document (protocol, clinical study report and informed consent) writing. Animations will be used as much as possible to illustrate genetic concepts. A few successful stories (case studies) of marketed pharmacogenomic drugs (e.g., oncology) will give a glimpse of what the industry has achieved so far.

Andrea Palluch

Andrea got her first job in the industry in 1999 armed with a degree in genetics, and an interest in molecular biology and immunology, as well as in clinical and applied research. Working as a CRA for 6 years and as a medical writer for the last 9 years, she gained considerable experience of pharmacogenomic studies during the decade which saw most advances in the human genome project. Andrea has previously served as EMWA's PR officer (2009-2011) and is now a member of the EMWA Professional Development Committee.

MSF6 Why do Drugs and Medicines have Adverse Effects?

Profile: Participants should, ideally, have already completed Introduction to Pharmacokinetics (DDF7) and Pharmacology for Medical Writers: Part 1 – The Basics (MSF1), or have equivalent experience or knowledge.

Objective: This workshop is designed to explain the reasons behind the commonest types of adverse effects of drugs and medicines. This is intended to enable participants to understand and often predict adverse effects of new drugs and

medicines. This will make it easier for participants to write accurately and effectively about the adverse effects of the drugs and medicines they will meet in their work.

Content: All effective drugs (and hence the medicines that contain them) have adverse effects. To be useful, therefore, the effective (i.e. therapeutic) dose of a drug or medicine must produce only acceptable adverse effects. Adverse effects can arise in several ways, and this workshop seeks to describe these in a systematic way. The mechanisms can be broadly summarised as follows:

(1) Extended normal pharmacology
(2) Parallel pharmacology
(3) Idiosyncratic reaction
(4) Pharmaceutical
(5) Pharmacokinetic interaction
(6) Pharmacological interaction
(7) Chemical interaction

Each of these mechanisms will be described with suitable examples, and the clinical significance of the different types of interaction will be discussed. Because of its largely factual content, the workshop will be mainly didactic. However, attendees will be expected to participate by answering questions as the presenter develops the explanations.

John Carpenter

John, a pharmacologist, was a lecturer in pharmacology at Manchester University from 1974 to 1992, where he studied drugs and the movement of ova through oviducts, anti-asthma drug models, and the pharmacokinetics of alcohol (never a shortage of volunteers). He has written or contributed to several pharmacology textbooks, and acted as an expert witness in court cases involving alcohol. In 1992, he became a full-time medical writer, initially with Gardiner-Caldwell Communications, then as Medical Team Director at Medical Action Communications and briefly as Medical Director at OCC. Since 2001, he has been a freelance medical writer, medical communications consultant, and trainer. John is a regular contributor to the range of training courses offered by the Proper Medical Writing Group in Poland and by Kemic Bioresearch in Canada. Satisfied customers include the Canadian Government's medicines regulatory department. He has served on the EMWA Executive Committee as Universities Liaison Officer and was a member of the EMWA Professional Development Committee (EPDC) from 2005 to 2010.

MSF7 Fundamentals of Immunology

Profile: This workshop is intended for medical writers with little or no background in immunology or those who are interested in refreshing their knowledge on the basic principles of immunology

Objective: The purpose of this workshop is to introduce medical writers (irrespective of their area of specialisation or the nature of documents they work on) to the basic principles of immunology. The ultimate aim of the workshop is to enable medical writers to better understand fundamental immunological concepts which in turn helps to better interpret the meaning of the results of clinical trials.

Content: The workshop will cover the following aspects: structure and functioning of the immune system, types of immunity and interactions, and immune system related disorders.

Based on the preworkshop assignment, two different group activities will take place to co-create a glossary of specific terminology/concepts in immunology.

Uma Swaminathan

Uma's passion for medical writing brought her all the way from Bangalore (India) to Belgium. During her Scientific Writing career of over 7 years at GSK, Uma has worked on a wide range of regulatory and disclosure documents across different vaccine projects. Following her stint in Medical Writing, Uma headed the Web Disclosure Team in GSK Biologicals which allowed her to further develop her skills in the field of project management, medical governance and scientific communication. These included such diverse activities as understanding and complying with the complex and ever-changing legal and regulatory requirements for disclosure; planning, tracking and delivery of protocol and results summaries; cross-functional training; and increasing the public disclosure awareness within the company. Uma then set up the Clinical Process Excellence Team in GSK Biologicals with oversight for process and written standards simplification in the human subject research space across all Clinical Delivery functions and transversally for the activities directly impacting clinical trials. Uma then moved to GSK Pharmaceuticals to head the Clinical Development Policy and Process group that drives consistency, accountability and continuous improvement in the way clinical development processes are governed, created, documented and continuously improved. Uma's assignment as Ethics & Compliance Direct or in Vaccines focused on enabling value-based decision making and smart risk taking while maintaining quality and compliance. In her current role as Head of R&D Bioethics & Policy, Uma and her team support the Chief Medical Officer in establishing patient focused and pragmatic R&D Policies.

MSF9 The Basics of Genetics for Medical Writers

Profile: This workshop will give a basic understanding of genetic principles to any writer who may need to understand or write about pharmacogenetics or genomics, or with an interest or curiosity in the field. It will also be useful revision for anyone

who has not been involved in the area for some time. No prior knowledge is necessary. Participants may find this a useful preparatory workshop for MSF4, Pharmacogenomics, at future conferences.

Objective: An understanding of genetics is becoming increasingly important in the pharmaceutical industry as the sciences of pharmacogenetics and pharmacogenomics grow and influence most aspects of drug research and development. As professional communicators, it is vital that medical writers have a basic understanding of genetics to be able to communicate the latest research and its effects correctly and effectively to regulators, healthcare professionals and even patients. Unfortunately, this area of science is often explained poorly or confusingly, and academic research papers assume a certain level of genetics knowledge. This workshop is intended to give a grounding in genetics, to explain basic genetic terminology and nomenclature, and to introduce writers to genetic research. The aim is that participants will be equipped to both cope with more advanced workshops involving pharmacogenomics, and to understand and interpret genetics research more easily.

Content: Participants will be led through the basics of inheritance, from the behaviour of DNA in cell division, through to inheritance patterns and how these may be predicted. Advances in sequencing and advanced topics such as pharmacogenomics, medical genetics, and epigenetics will be mentioned but detailed descriptions are beyond the scope of this workshop. The correct nomenclature and syntax will be explained (e.g. how to differentiate between genotype and phenotype).

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EUROPEAN MEDICAL WRITERS ASSOCIATION

Lisa Chamberlain James

Lisa is a Senior Partner and CEO of Trilogy Writing & Consulting Ltd. Aside from management activities, she leads client projects, with extensive experience in a variety of documents. Lisa has a special interest in writing for the general public and in patient information. Following a PhD and post doc. in Pathology at Cambridge, Lisa began her medical writing career in 2000. Since then she has also been involved in the European Medical Writers Association (EMWA) as a member of the Educational Committee, mentor, leader, and assessor of workshops, and teaches and reviews workshops for the American Medical Writers Association. Lisa holds an EMWA professional development certificate, is a member of TOPRA, DIA, and PIPA, initiated the EMWA PV Special Interest Group, is chair of the Geoff Hall Scholarship Committee, and is a Fellow of the Royal Society of Medicine.

MSF9a The basics of Genetics for Medical Writers

Profile: This workshop will give a basic understanding of genetic principles to any writer who may need to understand or write about pharmacogenetics or genomics, or with an interest or curiosity in the field. It will also be useful revision for anyone who has not been involved in the area for some time. No prior knowledge is necessary. Participants may find this a useful preparatory workshop for MSF4, Pharmacogenomics, at future conferences.

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PTA10 Effective Reporting of Scales, Questionnaires and VAS

Profile: This workshop addresses writers dealing with or interested in areas of clinical research, such as psychiatry, pain, quality of life, or health outcomes, where "soft" endpoints are often used to assess treatments. Participants should have at least 1 year of medical writing experience and should already have written a study report or a manuscript based on the results of clinical studies.

Objective: This workshop explains the use of assessments in treatment outcomes that cannot easily be measured objectively. Typical examples are patient or physician questionnaires and visual analogue scales. These are often used in psychiatry, pain studies, or quality of life research where objective measurements are not possible or difficult. The reporting of these "soft endpoints" has some pitfalls, often providing a huge amount of data that is difficult to analyze and interpret. Given the growing importance of psychiatry and quality of life research, scales and questionnaires are becoming more and more important for medical writers.

Content: Why are "soft endpoints" used in clinical research? What are typical examples of questionnaires? How should the measurements be selected (validation, generic vs. specific measures, acceptance)? How can results be evaluated and interpreted, including calculation of scores and subscores, and frequently used statistical analyses? How can results be communicated effectively without overwhelming the reader by the sheer amount of data? What needs to be taken into account when interpreting and discussing the results of questionnaires?

Thomas Wagner

Thomas is a biologist by training and was working hard to unravel the mysteries of the brain using his own brain and such obscure things as glass needles, fluorescent dyes and white powders called neurotransmitters. However, in order to avoid going

mad himself, he quit university and started his medical writing career in 1999 with the CRO Kendle in Munich. In 2002 he changed to big pharma and worked for Lilly Deutschland GmbH, mainly writing on Phase III-IV projects, including observational studies. Still working in the area of madness he mostly tackled psychiatry, quality of life, and red tape in the position of Group Leader Scientific Communications Europe for Neurosciences at Eli Lilly & Co. To avoid getting entangled too much he then changed in 2009 to the other side of the fence now working as a service provider and consultant for Trilogy Writing & Consulting as Medical Writing Manager. In 2015 Thomas moved to the headquarters of Merck Healthcare KGaA in Germany and is responsible for all regulatory medical writing documents from Phase I to post-marketing studies in the "beyond oncology" area; including the setup of a MW hub in Bangalore/India.

PTA11 Strategies for Improving Document Quality

Profile: This workshop is suggested for experienced medical writers, particularly those who are in a supervisory role, or who will soon be taking on that responsibility.

Objective: This workshop is designed to provide insights into effective policies and procedures that contribute to document quality. On completion of the workshop and class exercises, participants should be better able to apply pragmatic methods and behaviours that enhance awareness of the elements of document quality and lead towards more effective management of the process.

Content: Improving the process of document preparation is crucial for medical writers. Discussion will include mechanisms for enhancing quality and accountability, and for ensuring adequate time allowances. These are organisational issues around which a medical writing group can build policies aimed at ensuring a higher degree of accountability among those with whom they work and upon whose input they depend. Quality measures established by authoritative standards, as well as those that may be developed internally, are explored. Suggestions for effective management and departmental structure will also be provided.

Art Gertel

Art has a background in neurophysiology and behavioural medicine. As an independent consultant, he specialises in regulatory strategy, Data Safety Monitoring Board management, medical writing, and bioethics. Art has held senior posts at a number of companies including Schering-Plough/Merck, Hoffmann-LaRoche, TFS, and Quintiles, and headed departments responsible for medical writing, publications, project management, and regulatory affairs. He also served as a Senior Research Fellow with the Centre for Innovation in Regulatory Sciences (CIRS). Art has extensive teaching experience and has presented to professional organisations (e.g. EMWA, AMWA, DIA), and corporate and academic audiences, worldwide. He spent 2 years heading Clinical Operations for an eDC 'dot.com' company, and has been

active in CDISC since its inception. He served as Chair of the Global Ethics and Regulatory Initiative (GERI) of the Alliance for Clinical Research Excellence and Safety (ACRES). He is a Founding Member of the Global Alliance of Publication Professionals (GAPP), a Past President of AMWA, and a Fellow of both AMWA and EMWA. Art served in a Senior Advisory capacity on the Budapest Working Group in developing the CORE Reference. He has a particular interest in bioethics in the context of clinical studies, is an advisor to an IRB, and serves on a number of task forces focusing on improving the drug development process while protecting the rights and safety of clinical study participants.

PTA12 Interpersonal Skills for Medical Writers

Profile: Anyone who wants to explore effective and diplomatic ways of overcoming common interpersonal hurdles that arise in the course of every day life as a medical writer.

Objective: To think about the role of the medical writer as a team mediator and to learn how to solve common interpersonal problems, either by avoiding them in advance or by understanding the issues that need to be addressed once they have occurred.

Content: As medical writers, we deal with many different people (some with very large egos and very little diplomacy) to prepare the documentation we are expected to write. This workshop will present and discuss the basic philosophy of the role of a medical writer in the social context. We will look at our role on a project team in terms of team dynamics as well as how we interact with people on a one-on-one basis. Real-life examples (good and bad) and hands-on exercises followed by discussion will demonstrate how to use different approaches in different contexts to minimize interpersonal conflicts and overcome those that occur.

Julia Forjanic Klapproth

Julia Forjanic Klapproth is a poet and scientist who stumbled onto medical writing in 1997. With a PhD in developmental neurobiology and a passion for writing, she enjoys the challenge of grappling with the science while crafting it into easily understandable text. Julia has worn various guises for the good of EMWA over the years including twice being President (2007-2009 and in 2002). In 2002 she co-founded the medical writing company Trilogy Writing & Consulting in Germany and is a Senior Partner. Julia is passionate about medical writing and teaches writers on a broad range of topics.

PTA13 The Art of Mentoring

Profile: Participants who already mentor other writers or those who may soon be given the role will benefit from this workshop, including those who take on the role voluntarily and those who are more hesitant about their abilities. Most participants will have been medical writing for at least 2-3 years and will have a good foundation in their chosen career path.

Complementary workshops: PTA11 – Strategies for Improving Document Quality and PTA12 – Interpersonal Skills for Medical Writers.

Objective: The aim of this workshop is to give both new and experienced mentors an open and encouraging environment for learning, developing and sharing mentoring skills. The workshop has been devised to inspire and enthuse participants in what is at times a challenging, yet highly rewarding role. After completion of the workshop and class exercises, participants should have a raised awareness of their role as mentors and the impact they may have on their mentees, teams and product quality. The workshop will also discuss strategies to diplomatically manage the varied situations that mentors may encounter.For 2021, we will focus on mentoring virtually.

Content: This workshop will cover how mentoring can add significant value to teams and drive improvements in product quality; how to mentor in a holistic manner; how to vary mentoring style according to different mentee personalities; how to allow mentees to develop individually; and how to learn from mentees and develop personally through the mentoring role. Setting up and coordinating mentoring systems is outside the scope of this workshop.

Sarah Tilly

Sarah values the people with whom she writes in the same way she values the patients about whom she writes, and the customers for whom she writes. She believes that everyone has their own, unique contribution to give to our industry. For this reason, Sarah has been involved in mentoring new medical writers since an early stage of her career. In parallel with her largely regulatory writing experience, she has managed and mentored several teams of writers and has been involved in setting up and coordinating training systems. Sarah has been medical writing since 2006 in clinical research organisations and medical writing consultancies. She set up Azur Health Science in 2017 as Medical Writer and Director. She holds a first degree in Biology and a PGCert in International HTA, Pricing and Reimbursement.

PTA14 Building Medical Writing Teams

Profile: Managers of writing teams (in-house or freelance), experienced writers looking for a career path into management, freelancers working working in networks or in a team, and those who are interested in building network-teams. The workshop mainly focuses and draws examples from regulatory writing teams.

Complementary workshops: PTF8–Cross-cultural communication, PTA11–Strategies for Improving Document Quality, PTA12–Interpersonal Skills for Medical Writers, PTA13–The Art of Mentoring.

Objective: Participants should have a greater understanding of the unique and varied composition of medical writing teams and the strategies and skills that can be used to build, manage and expand dynamic teams of writers in any writing environment.

Content: We will discuss how team leaders and managers can use a variety of strategies and skills to build, manage and expand teams of writers, and how they can harness each members' skills, knowledge and expertise to ensure production of high quality work within budgeted hours and timelines. We will also cover establishing a team atmosphere to provide an encouraging environment for learning, developing and sharing writing skills at the level, need and desire of each team member.

The workshop will cover:

- What a real team looks like
- How a real team functions and develops
- How experienced writers benefit from the team model
- Freelancers as part of the team
- Global teams – team cohesion, distance communication
- Expanding the team
- Retention strategy and succession planning

Jules Kovacevic

Jules has been working in the CRO environment since 2006, focussing in medical affairs and medical writing and a member of EMWA since 2014. She has been actively involved in writing, budgeting, resourcing and training in medical writing for the last 12 years, particularly focusing on online training and webinars for the last few years. Successfully setting up teams in a variety of organisations and being actively involved in the development of individual writers has become a major part of her working life. In her current role as Head of Medical Writing at Ergomed, she has managed, trained and developed a global team of medical writers of varying experiences, both employees and contractors, all through online platforms and mediums. Jules runs an EMWA workshop on building medical writing teams where she shares the team model that is focussed on personal development in order to promote a positive work environment, staff satisfaction, staff retention, skill development, and a clear career path within the medical writing function. She is a member of the EPDC, taking a lead, with Laura Collada Ali, on the EMWA webinar programme.

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PTA16 Oral Presentations: Skills to Help You Survive or Even Shine

Profile: This workshop is suitable for medical writers who have some experience in delivering oral presentations and want to reflect on or improve their oral presentation skills.

Objective: Participants should find the workshop useful for a variety of situations: presentations to colleagues, pitching to potential clients for new business, training colleagues, or speaking at meetings. Participants should be confident communicating in English, particularly as they will deliver a short presentation in English. (We do not cover slide design and construction of a story, which is addressed in the workshop Developing Effective Oral Presentations, MCF22.)

- Appreciate that good preparation and rehearsal are key to successful delivery.
- Consider how good presenters engage their audience: use of voice and body language.
- Learn how to deal with questions and challenging people.
- Handle presentation nerves.
- Gain practical experience and receive feedback by delivering a short presentation during the workshop.
- Constructively critique the short presentations delivered by other workshop participants.

Content:

- What you need to know before preparing slides.
- Managing equipment and the environment.
- Rehearsing and keeping to time.
- Increasing the impact of an oral presentation.
- Presentation nerves.
- Voice and body language.
- Questions and difficult people.
- Individual participant presentations.

Important

Each participant will deliver a short presentation (3 minutes) with up to 10 slides prepared during the pre-workshop assignment. Participants and workshop leader will give constructive feedback.

- The workshop is limited to 10 participants, allowing comfortable time for all presentations and feedback.
- For those who are worried – don't be – you'll be safe and it's fun!

John Dixon

John qualified in medicine having studied at Oxford University and Guy's Hospital, London. Initially he trained as a surgeon. After gaining further experience in paediatrics, neonatology, obstetrics and gynaecology, he then became a GP. Since

2003, John has completed an MBA at Warwick University Business School. He then spent five years as Director of Medical Communications at InterComm International Ltd., becoming a healthcare communications consultant and trainer in scientific communications in 2013. His interests include supporting researchers, medical communications agencies and medical equipment companies to ensure their scientific communications are accurate, understandable and use appropriate language. John has provided training for universities and research institutes across Europe in academic writing, presentation delivery, and conference abstract and poster preparation. He is a member of EMWA's Professional Development Committee and also provides a workshop: 'Using readability tools to help edit biomedical research articles'. He is coauthor of How to Publish in Biomedicine. 500 Tips for Success. 3rd Edition (2016). CRC Press.

PTA17 Graphical Abstracts

Profile: Graphical abstracts are a unique way to communicate scientific information visually. Often such visualisations are requested by journals to be submitted as publication extenders. Those who stand to benefit from this workshop are medical writers & communicators in the pharmaceutical industry, CROs, medical writing agencies, and academic institutions who are involved in the preparation of scientific publications.

Objective: The intention of this workshop is to educate medical writers & communicators on the basic concept of graphical abstracts using Microsoft PowerPoint 365®.

Content: The Graphical Abstract workshop will provide an overview of key elements of graphical abstracts, how to create graphical abstracts using Microsoft PowerPoint 365®, and what the current requirements for graphical abstract submission and publication are.

Carola Krause

Based in Potsdam, Germany, Carola Krause has been offering a professional biomedical writing consultancy service to the pharmaceutical industry since 2016. Carola is a postdoctoral molecular cell biologist with hands-on experience in basic and pharmaceutical research and development. Her multidisciplinary background in academic and pharmaceutical project management and clinical trial coordination provides her with key insights into all phases of the drug development process and its regulatory requirements. She has 15 years of experience in biomedical communication and has attended EMWA workshops since 2014. Carola is the chair of EMWA's Creative team, co-founded the Sustainability Special Interest Group and has served as EMWA's (Vice)President from 2020–2022.

EUROPEAN MEDICAL WRITERS ASSOCIATION

PTA18 From pre-IND and CTA to submission: the Medical Writer as the leader and manager

Profile: This workshop is beneficial for Medical Communicators/Medical Writers (MW) who lead in project development, resource for specific documents, possibly still author, or manage teams and resource tasks within those teams. Participants should have experience of leading projects, departments, teams or with the potential of moving into that role.

Objective: This workshop will detail and enhance stakeholder management and resource management within project teams when the MW is considered the lead in the production process. MWs will be in a position to better manage the projects that they are leading or resourcing following this workshop.

Content: The structure of the workshop is proposed to be looking at different stages of document development, starting with pre-IND, then moving to study level documents, programme level and finally submission packages.

Sarah Choudhury

Sarah has been a medical writing professional since she graduated with a doctorate in the biological sciences from University College London. Currently, she is a Director in Clinical regulatory writing at AstraZeneca. Her current role involves managing all the writing activities of Oncology programs, of an NME and established compounds across INDs to MAAs, BLAs and other regional submissions. Previously, she has worked in CROs, other pharmas, both as a manager and lead author. In addition to working in medical devices, and as a freelancer. She is actively involved in EMWA as a member and conference attendance to obtain both her EPDP certificates. Then served on the Executive Committee as Treasurer and Honorary Secretary, led an EMWA workshop, EMWA webinar, and published in Medical Writing. She is currently part of the Treasurer's Finance Committee and leads the and the RemunerationSurvey team.

Andrew Balkin

Andrew has worked in clinical research for more than 20 years, both for both big pharma (and small pharma) and CROs. He has worked on an extensive range of regulatory documents covering all phases of clinical trials and has a background in virology (and was involved in product launches for numerous ground-breaking antiretroviral and HCV treatments). Andrew also spent many years as a medical writing specialist in rare diseases and has worked for BBC Health. He has managed MW teams in pharma and CROs, and currently manages the global medical writing team in a mid-sized CRO.

Andrew is a relatively new member of the European Medical Writers Association (EMWA) and is a member of the Regulatory Writing Special Interest Group. He is

relishing the opportunity to increase his involvement with EMWA and to further contribute to their ground-breaking activities.

PTA2 Do More with Less Faster: Project Management for Biomedical Communications

Profile: Delegates should include medical writers, particularly those who work within, or for, pharmaceutical companies; project managers (whether by actual title or function); and others with responsibility for overseeing and coordinating multifunctional projects. Participants should have at least 1 year's experience working within a matrix environment.

Objective:

- Acquire understanding of basic project management theory
- Apply project management theory to multifunctional projects
- Broaden context beyond medical writing
- Add team-building strategies

Content: Discussion will include project management theory and practical applications, both within the context of a matrix organisation, and as an independent providing services to clients. A medical writing group may also adopt these practices to better control their own destiny.
This workshop will be a combination of lecture and in-class exercise, and will include discussions based on analysis of the scenarios presented in the homework. While the majority of the presentation will be didactic, there will be opportunity for attendees to share their experiences and ask questions throughout the presentation.

Art Gertel

Art has a background in neurophysiology and behavioural medicine. As an independent consultant, he specialises in regulatory strategy, Data Safety Monitoring Board management, medical writing, and bioethics. Art has held senior posts at a number of companies including Schering-Plough/Merck, Hoffmann-LaRoche, TFS, and Quintiles, and headed departments responsible for medical writing, publications, project management, and regulatory affairs. He also served as a Senior Research Fellow with the Centre for Innovation in Regulatory Sciences (CIRS). Art has extensive teaching experience and has presented to professional organisations (e.g. EMWA, AMWA, DIA), and corporate and academic audiences, worldwide. He spent 2 years heading Clinical Operations for an eDC 'dot.com' company, and has been active in CDISC since its inception. He served as Chair of the Global Ethics and Regulatory Initiative (GERI) of the Alliance for Clinical Research Excellence and

Safety (ACRES). He is a Founding Member of the Global Alliance of Publication Professionals (GAPP), a Past President of AMWA, and a Fellow of both AMWA and EMWA. Art served in a Senior Advisory capacity on the Budapest Working Group in developing the CORE Reference. He has a particular interest in bioethics in the context of clinical studies, is an advisor to an IRB, and serves on a number of task forces focusing on improving the drug development process while protecting the rights and safety of clinical study participants.

PTA3c Slippery Slopes: Survival Analysis

Profile: The workshop is for everybody who has come into contact with the statistical technique of Kaplan-Meier survival analysis and who wants to know more about what it means. Ideally you should have encountered such analyses in the context of clinical trials.
Some minimal statistical understanding is needed and terms like 'median', 'mean', 'confidence interval', 'risk' , and 'p-value' should not terrify you.

Objective: The objective is to acquire a basic understanding of Kaplan-Meier analyses and to be able to interpret the resulting graphs.

Content: The workshop will give participants an understanding of the analysis of survival in the context of clinical trials. We will learn the basics of creating and interpreting Kaplan-Meier graphs and the different elements of reporting Kaplan-Meier analyses. The appropriate graphical and tabular presentation of these analyses will be discussed, but always the focus will be on the interpretation. There will be a few group exercises during the course.

Thomas Schindler

Thomas M Schindler studied biology and linguistics in Germany and the UK, obtained a PhD in molecular physiology, and did postdoctoral research in the UK. Thereafter, he became an editor of popular science books in biology, geography, and astronomy. He then turned to medical writing and has now gained some 25 years of experience in both medical affairs and regulatory medical writing including the preparation of all documents for marketing authorization applications around the globe. He founded and established the medical writing function at Boehringer Ingelheim and has recently headed the Innovation Medical Writing Group focussing on lay communication, good graphics development, video creation and AI-driven writing.
He was a member of the TransCelerate Return of Results work stream, is contributing to the Good Lay Summary Practice initiative and the PFMD Plain Language Summary guidance.

PTA3d Slippery Slopes: Survival Analysis

Profile: The workshop is for everybody who has come into contact with the statistical technique of Kaplan-Meier survival analysis and who wants to know more about what it means. Ideally you should have encountered such analyses in the context of clinical trials.
Some minimal statistical understanding is needed and terms like 'median', 'mean', 'confidence interval', 'risk' , and 'p-value' should not terrify you.

Objective: The objective is to acquire a basic understanding of Kaplan-Meier analyses and to be able to interpret the resulting graphs.

Content: The workshop will give participants an understanding of the analysis of survival in the context of clinical trials. We will learn the basics of creating and interpreting Kaplan-Meier graphs and the different elements of reporting Kaplan-Meier analyses. The appropriate graphical and tabular presentation of these analyses will be discussed, but always the focus will be on the interpretation. There will be a few group exercises during the course.

Thomas Schindler

Thomas M Schindler studied biology and linguistics in Germany and the UK, obtained a PhD in molecular physiology, and did postdoctoral research in the UK. Thereafter, he became an editor of popular science books in biology, geography, and astronomy. He then turned to medical writing and has now gained some 25 years of experience in both medical affairs and regulatory medical writing including the preparation of all documents for marketing authorization applications around the globe. He founded and established the medical writing function at Boehringer Ingelheim and has recently headed the Innovation Medical Writing Group focussing on lay communication, good graphics development, video creation and AI-driven writing.
He was a member of the TransCelerate Return of Results work stream, is contributing to the Good Lay Summary Practice initiative and the PFMD Plain Language Summary guidance.

Elisabeth Kuhn

Elisabeth is a biologist by training and received her PhD in the field of oncology, focusing on paracrine cell-cell interaction. After having experienced the benchside of research for several years, she decided to move over to the bedside and help to bring innovative drugs to market. As she always enjoyed the interpretation and presentation of data, medical writing was a perfect fit. Since 2012, she has been working as a regulatory medical writer at Boehringer Ingelheim Pharma GmbH & Co. KG. She is involved in various oncology projects across different indications and writes Phase III CSRs and clinical summary documents.

PTA4 Data Presentation II: Advanced Data Presentation

Profile: Medical writers and editors with 2–4 years of experience.

Objective: At the end of the course participants should be able to:

- Choose an appropriate data presentation form when given data in raw form or in paragraph style
- Recognise some of the different types of data presentation forms
- Understand the different functions of these forms
- Identify the strengths and weaknesses in the design of a given data presentation and be able to modify it accordingly

Content: The role of a medical writer is to be able to present data in the clearest and most understandable form possible. Although medical writers work largely with tables and graphs, there are other, more advanced forms with specialised uses. These presentations can be very powerful when used correctly but are easily misused by the unwary. In this course, participants will learn about advanced tools of data presentation: flow charts, pie charts, box plots, contingency tables, icon displays, as well as more specialised forms. The components and specialised uses of each different type, as well as rules for their optimal use will be explored. It is helpful but not necessary if participants have taken the EMWA 'Data Presentation I' workshop.

Barry Drees

Barry Drees was a witness to the start of the genetech madness when he got his PhD in molecular genetics at the University of California at San Francisco at the time of the founding of Genentech. Life's sense of irony took him to Germany, however, where he worked as a medical writer in the pharmaceutical industry for 12 years, setting up a Phase I writing group and leading several regulatory submission teams, among other activities. Barry is a frequent speaker on medical writing, statistics and other scientific communication topics for Management Forum Ltd, as well as various pharmaceutical associations. He also speaks on non-scientific topics such as the introductory presentation on the history of Malta at the 20th EMWA conference. He has appeared on an educational television programme in Germany to discuss the ethics of genetic engineering and German radio to discuss medical writing as a career. He is the former Editor-in-chief of 'The Write Stuff', the Journal of EMWA (now called 'Medical Writing'), and is currently a Senior Partner at Trilogy Writing & Consulting. He served on the EMWA Professional Development Committee (EPDC) 2006-2009, with a focus on Train-the-Trainer events. Barry is a Nick Thompson Fellow of EMWA.

PTA5 Interpreting and Reporting Diagnostic Test Characteristics

Profile: This workshop is for experienced medical writers who want to learn how to interpret and to report the performance characteristics of diagnostic tests.

Objective: Participants completing the workshop will be able to identify, interpret, compute, and appropriately use the most common diagnostic test characteristics used in biomedical research.

Content: Topics will include sensitivity and specificity, predictive values, likelihood ratios, and Bayesian statistical reasoning, as well as issues related to definitions of normal, equivocal test results, and implementing a new test into clinical practice. The workshop is based on Chapter 10, "Reporting Diagnostic Tests", of "How to Report Statistics in Medicine: Annotated Guidelines for Authors, Editors, and Reviewers", Second Edition, by Thomas A. Lang and Michelle Secic (American College of Physicians, 2006).

Tom Lang

Tom has been a technical writer since 1975 and has spent much of that time specialising in the critical appraisal and documentation of biomedical research and in studying evidence-based techniques for improving written communication. He is the author of "How to Report Statistics in Medicine", a standard reference for reporting evidence-based medicine, and teaches medical writing at the University of Chicago, as well as to a variety of clients in North America and Asia. A Past President of the Council of Science Editors, he has also received teaching awards from the University of Chicago, The American Statistical Association, and AMWA. His goal is to increase the professional standing of medical writers by disseminating the bodies of knowledge and skills that are unique to the profession.

PTA6 Scheduling and Proposal Writing: The Clinical Study Protocol and Report

Profile: Medical writers working in the contract research organisation or pharmaceutical company environment, as either employees or as freelancers. The workshop will meet the needs of writers often working to tight protocol and study report writing timelines because of inadequate scheduling of the processes leading up to and driving preparation of these documents. This is an ideal forum for writers whose organisations or clients have scope to improve their analysis and reporting processes and procedures.

Objective: Protocol writing heralds the start of the trial documentation and reporting process; the study report is often the final document prepared by medical writers. Exacting and sometimes unrealistic timelines for deliverable preparation are often agreed without consultation with the medical writer. The workshop discusses the stages before and during preparation of these documents to show how achievable timelines may be scheduled, thereby facilitating good proposal writing. After completing the workshop, participants will understand the stages involved so they can make a valuable contribution to their organisation's or client's process

improvement activities and are better equipped to manage client expectations with regard to efficient, effective and realistic proposal writing and project scheduling.

Content:

- Bidding and project award process
- First steps on contract win and allocation of study
- Contract review and confirmation of scope
- Communication with client and functional groups
- Scheduling
- Study protocol: stages of preparation
- Clinical study report: stages of preparation
- Proposal writing
- Business advantages of effective scheduling, influencing the process, and managing expectations

Sam Hamilton

Sam Hamilton is a postdoctoral virologist, with 28 years in clinical and regulatory medical writing and leadership roles in the pharmaceutical industry. Sam has a special interest in public disclosure of clinical-regulatory documents as Chair of the EMWA-AMWA group who delivered the open-access www.core-reference.org in May 2016. Sam is long-time supporter of EMWA serving in various roles over 15 years, notably as Freelance Advocate; Editorial Board member for Medical Writing (MEW); Workshop Leader; Expert Seminar Series (ESS) Chair; and Vice President and President. Sam was elected an EMWA Nick Thompson Fellow in 2018 for her services to the Association. Sam is currently MEW Section Editor for the "Regulatory Public Disclosure" Section, and Chair of The CORE Reference Project.

PTA8 Statistical Analysis of Binary Data

Profile: Medical writers who wish to understand the analyses of binary data (i.e. yes/no outcomes such as death, response to treatment etc.). Participants should be familiar with basic statistical concepts such as P-values and confidence intervals.

Objective: To gain familiarity with some of the techniques used for analysing binary data and the various measures of association, such as odds ratios or relative risks, used in analysing binary data.

Content: The workshop will focus on understanding what the various statistical tests are, why they are done, and how to interpret the results. This will not be a tutorial in how to do the statistical tests (other than some of the simplest ones), as it is assumed that participants will generally receive the results of analyses from statisticians and be given the job of interpreting those results.

- Definitions of binary data

- Simple statistical tests to compare binary data in 2 treatment groups: chi-squared test and Fisher's exact test
- Measures of association of binary variables: odds ratios, risk differences, relative risks
- The Mantel-Haenszel test and other more sophisticated analyses
- Logistic regression: the most powerful technique for analysing binary data

Adam Jacobs

After getting bored of his first two careers (organic chemistry research and medical translating), Adam worked as a medical writer, first at a small contract research organisation and then at a large medical communications agency. He set up his own business in 1999, which was a lot of fun for a while but sadly didn't survive the recession and ceased trading in 2014. Adam was EMWA President in 2004–2005 and was co-author of EMWA's guidelines on the role of professional medical writers in publications. He finally got bored of medical writing as well, and now works as a statistician. However, he doubts he will ever get bored of coming to EMWA conferences.

PTA9 Analysis of Variance and Regression Analysis

Profile: Medical writers who wish to understand analysis of variance, linear regression, and other methods for the analysis of normally distributed continuous data. Participants should be familiar with basic statistical concepts such as P values and confidence intervals.

Objective: To understand the methods used for analysing continuous data, to appreciate that analysis of variance and linear regression are essentially the same analyses but presented in different ways, to understand some of the assumptions underlying the analyses, and to learn what features of the analyses are important for medical writers to present when describing analyses.

Content: The workshop will focus on understanding what the various statistical tests are, why they are done, and how to interpret the results. This will not be a tutorial in how to do the statistical tests (other than some of the simplest ones), as it is assumed that participants will generally receive the results of analyses from statisticians and be given the job of interpreting those results.

- Normal distribution
- Dependent and independent variables
- The T-test: the simplest test for analysing normally distributed data
- One-way ANOVA for comparing more than 2 groups
- Simple linear regression
- Multiple linear regression and more complex ANOVA models
- Understanding ANOVA and regression output

Adam Jacobs

After getting bored of his first two careers (organic chemistry research and medical translating), Adam worked as a medical writer, first at a small contract research organisation and then at a large medical communications agency. He set up his own business in 1999, which was a lot of fun for a while but sadly didn't survive the recession and ceased trading in 2014. Adam was EMWA President in 2004–2005 and was co-author of EMWA's guidelines on the role of professional medical writers in publications. He finally got bored of medical writing as well, and now works as a statistician. However, he doubts he will ever get bored of coming to EMWA conferences.

PTF1 Data Presentation I: Tables and Graphs

Profile: Medical writers and editors with 0-4 years of experience

Objective: At the end of the course participants should be able to:

- Compose a table or graph when given data in raw form or in paragraph style
- Recognise the basic parts of a table and a graph and identify the various types of tables and graphs
- Understand the functions of tables and graphs
- Identify the strengths and weaknesses in the design of a given table or graph and be able to modify it accordingly

Content: The role of a medical writer is to be able to present data in the clearest and most understandable form possible. The best way to present and communicate with data, however, is not prose but rather using some form of graphical presentation. This course will challenge and stimulate the participants' ability to think clearly about the data they present and write about. Participants will learn about the basic tools of data presentation, tables and graphs, their types and components, and when—and when NOT—to use them. It will introduce the participants to the fundamental tools of data presentation, tables and graphs in all their myriad forms and uses. This course is an introduction to data presentation and should be taken before taking Data Presentation II: Advanced Data Presentation.

Barry Drees

Barry Drees was a witness to the start of the genetech madness when he got his PhD in mlecular genetics at the University of California at San Francisco at the time of the founding of Genentech. Life's sense of irony took him to Germany, however, where he worked as a medical writer in the pharmaceutical industry for 12 years, setting up a Phase I writing group and leading several regulatory submission teams, among other activities. Barry is a frequent speaker on medical writing, statistics and other scientific communication topics for Management Forum Ltd, as well as various pharmaceutical associations. He also speaks on non-scientific topics such as the introductory presentation on the history of Malta at the 20th EMWA conference. He

has appeared on an educational television programme in Germany to discuss the ethics of genetic engineering and German radio to discuss medical writing as a career. He is the former Editor-in-chief of 'The Write Stuff', the Journal of EMWA (now called 'Medical Writing'), and is currently a Senior Partner at Trilogy Writing & Consulting. He served on the EMWA Professional Development Committee (EPDC) 2006-2009, with a focus on Train-the-Trainer events. Barry is a Nick Thompson Fellow of EMWA.

PTF13 Critical Appraisal of Medical Literature

Profile: This workshop will be of use to all medical writers who need to read published medical papers and interpret their findings. Participants should have a basic grasp of trial design (parallel groups, crossovers, etc.) and recognition of (but not necessarily practical experience of using) common statistical tests (e.g. chi-squared, t-test).

Objective: After attending this workshop, participants should be able to assess the strengths and weaknesses of papers they read in the medical literature and be able to judge whether the published conclusions of the paper are valid.

Content: The workshop will explain what to look for when reading published papers, with emphasis on assessing strengths and weaknesses of the research described. This will include considerations of study design, sources of potential bias, use of appropriate statistical methods, choice of endpoints, and generalisability. The workshop will include practical exercises in critiquing papers in a group discussion format.

Adam Jacobs

After getting bored of his first two careers (organic chemistry research and medical translating), Adam worked as a medical writer, first at a small contract research organisation and then at a large medical communications agency. He set up his own business in 1999, which was a lot of fun for a while but sadly didn't survive the recession and ceased trading in 2014. Adam was EMWA President in 2004–2005 and was co-author of EMWA's guidelines on the role of professional medical writers in publications. He finally got bored of medical writing as well, and now works as a statistician. However, he doubts he will ever get bored of coming to EMWA conferences

PTF14 Time Management for Medical Writers

Profile: This workshop is aimed at all writers who find they have trouble fitting all their workload into a standard working week.

Objective: The purpose of this workshop is to look at the common problems people experience with managing their time and their workload and to suggest some ideas and techniques that can be used to help. On completion of the workshop package, participants should be able to assess their working pattern and be able to work out a more effective way of working while still having time for fun and socialising!

Content: The workshop will begin with a brief presentation on the common problems associated with managing time and workload. Various published time management techniques will then be reviewed, along with the pros and cons of each. Several fun exercises will be included to get delegates to think about the problems of time management and ways around them. Finally, there will be a review and summary of the key messages to bear in mind when back in the office.

Debbie Jordan

Debbie has been working in the pharmaceutical industry for over 30 years in both pharmaceutical company and CRO environments. She has worked as a data assistant, CRA and project manager, before moving into medical writing. Twenty years ago she set up her own medical writing company and now works on all aspects of medical writing from clinical development programmes and regulatory packages through to marketing and conference material. Debbie also provides training in medical writing and associated topics to a variety of organisations. Debbie has served on the Executive Committee of EMWA in the past and was a key member of the CORE reference working group.

PTF15 Interpreting and Reporting Measures of Risk

Profile: This workshop is for medical writers interested in understanding the most common rates, ratios, and measures of risk used in medical research.

Objective: Participants completing the workshop will be able to identify, interpret, compute, and appropriately use 11 measures of risk and the rates and ratios on which they are based. Participants will also become familiar with the potential for manipulating readers through the use and misuse of these measures.

Content: Eleven measures of risk and their associated rates and ratios will be taught, as well as the ethical implications of how risk is reported. The workshop is based on Chapter 2, "Comparing Probabilities of Events: Reporting Measures of Risks", of "How To Report Statistics in Medicine: Annotated Guidelines for Authors, Editors, and Reviewers", Second Edition, by Thomas A. Lang and Michelle Secic (American College of Physicians, 2006).

Tom Lang

Tom has been a technical writer since 1975 and has spent much of that time specialising in the critical appraisal and documentation of biomedical research and in

studying evidence-based techniques for improving written communication. He is the author of "How to Report Statistics in Medicine", a standard reference for reporting evidence-based medicine, and teaches medical writing at the University of Chicago, as well as to a variety of clients in North America and Asia. A Past President of the Council of Science Editors, he has also received teaching awards from the University of Chicago, The American Statistical Association, and AMWA. His goal is to increase the professional standing of medical writers by disseminating the bodies of knowledge and skills that are unique to the profession.

PTF18a Writing for the Internet

Profile: This workshop is suitable for any medical writer with an interest in writing for the internet, whether already involved in this type of writing or not.

Objective: Medical writers are increasingly asked to provide text for online use. The objective of this workshop is to outline the basic principles of writing for the internet. The emphasis is on understanding how online content differs to more traditional media. We will NOT cover technical aspects such as website design, style sheets, coding, hosting, and related issues

Content: We will review the basic principles of writing for the internet and consider how it differs from writing for print. How readers use the internet and the visual and structural aspects of presenting information online are also covered. We will examine different online writing structures such as the inverted pyramid technique. The importance of headings and sub-headings are also outlined. Other topics such as Search Engine Optimisation (SEO), metadata and calls to action will also be briefly touched upon. The workshop includes practical exercises on creating internet text. A selection of post-workshop assignments will be published on the EMWA website!

Diarmuid De Faoite

Diarmuid is an EMWA workshop leader and served as a member of the EMWA Executive Committee from 2012 to 2022. Originally an academic researcher on the subject of entrepreneurship, he has worked as a business lecturer and researcher, editor and writer in Ireland, Germany and Switzerland. After 15 years in orthopaedic clinical research, he worked for 2 years in communications in the intellectual property rights field. He is now back in medtech, working as the Key Expert Manager for a dental intraoral scanner company. Diarmuid is also a general freelance writer.

PTF19 An Introduction to Marketing for Medical Writers

Profile: Anyone who wants to gain a better understanding of the basic concepts and theories of marketing.

Objective: Participants will gain insights into how pervasive and persuasive marketing is, and how attention to detail can help them to improve both their own and their firm's image. By demystifying marketing, workshop participants can both identify and implement simple techniques in many elements of their daily work. Participants will have to bring their own marketing examples to the workshop for discussion. This thought-provoking workshop will lead you to view the process of marketing in a new light. (Please note that the main workshop focus is on general marketing theories and real-life examples drawn from different industries).

Content: Topics covered include the marketing concept, the marketing mix, buyer behaviour, the promotional mix, and strategic analysis. The workshop includes a mixture of lecturing, real-life examples, group activities and discussion.

Diarmuid De Faoite

Diarmuid is an EMWA workshop leader and served as a member of the EMWA Executive Committee from 2012 to 2022. Originally an academic researcher on the subject of entrepreneurship, he has worked as a business lecturer and researcher, editor and writer in Ireland, Germany and Switzerland. After 15 years in orthopaedic clinical research, he worked for 2 years in communications in the intellectual property rights field. He is now back in medtech, working as the Key Expert Manager for a dental intraoral scanner company. Diarmuid is also a general freelance writer.

PTF20 Introduction to Health Economics

Profile: The workshop will be non-technical and will assume no previous economic or statistical knowledge. It will benefit medical writers of all backgrounds who want an introduction to the rapidly growing field of health economics and its use in medical decision making.

Objective: The workshop will provide an introduction to some of the key concepts and terminology in health economics, as relevant to drug and device development, reimbursement and market access. The aim is to increase medical writers' confidence in working with the concepts presented.

Content: The workshop will cover the following topics:

- What is health economics? Why do we need a 'fourth hurdle'?
- The use of health economics in medical reimbursement across Europe
- Health-related quality of life/utility: what it is it, and how is it measured?
- Key principles of cost-effectiveness and economic evaluation. The terminology used and the importance of a reference case
- A short introduction to health economic modelling and the importance of incorporating uncertainty in reimbursement decision-making
- Health economics in clinical trials – what data needs to be collected and when?

Stuart Mealing

Stuart has worked in the field of health economics since 2004, initially in academia and then in the commercial sector. Stuart leads a team of health economic modellers at ICON Plc and has published the results of his analyses in a range of clinical and health economic journals. He has also been involved with the preparation of numerous submission dossiers for NICE and other authorities.

PTF21 Health-related Quality of Life

Profile: This workshop is aimed at medical writers who deal with health-related quality of life instruments (HRQoL) in clinical studies or document writing. No prior experience with HRQoL instruments is needed.

Objective: The workshop will give an overview of the different types of HRQoL instruments and the main issues to be considered when using these measures in clinical studies. Participants will learn how to appraise HRQoL measures and acquire a better understanding of HRQoL data.

Content:

1. What is HRQoL and why measure it?
2. Instruments for measuring HRQoL (generic vs. specific, profile vs. preference-based measures)
3. Using HRQoL instruments in a study
   - choice of measure
   - modes of administration
4. Reporting and interpreting HRQoL data

Claire Gudex

Claire is assistant professor in Academic Writing and health service researcher in the area of patient outcome measurement. She has a medical degree and worked for 10 years at the Centre for Health Economics, University of York, UK, before moving to Denmark in 1995, where she has worked at WHO Regional Office, National Institute of Public Health, and the University of Southern Denmark. Claire is a founder member of the EuroQol Group, an international research group for the development of the generic health measure, EQ-5D. She is section editor for the 'Teaching Medical Writing' column in the EMWA journal *Medical writing*.

PTF22 Managing the Clinical study Protocol Writing Process

Profile: This workshop is aimed at company staff and freelance medical writers who are interested in learning how they can make an effective contribution to the

protocol writing process by taking a leading role. Previous participation in the workshop on The Clinical Study Protocol is recommended.

Objective: The objective of this workshop is to present the process of study protocol preparation to medical writers as a type of project management. The emphasis will be on the process of how the medical writer can effectively lead the preparation, review, and finalization of a clinical study protocol as a member of a multifunctional team. Study protocol writing will not be discussed in detail.
Upon completion of this workshop, participants should be better prepared to work efficiently within a complex and at times quickly changing environment.

Content: The workshop will cover the role of the medical writer in leading the protocol writing process as a member of a multifunctional team.
Best practices (do's and don'ts) will be covered showing how a medical writer can best lead the team through the different steps in the process (from the kick-off meeting with the study team to the finalisation of the document)... Useful tools and practical approaches that can make the process easier will be presented.

Abraham Fred Shevack

Abe F. Shevack MA, ELS is a Biologist with many years of experience in basic research in both academia and industry. He is also a certified Editor in the Life Sciences. For over 20 years as a senior scientific medical writer at Schering and Bayer, Abe wrote numerous regulatory documents including clinical study protocols, investigator's brochures, study reports, and CTD documents for global regulatory submissions. He has worked in a wide range of therapeutic indications and has participated in successful global marketing authorizations for new drugs in leukemia, non-Hodgkin's lymphoma, hepatic cell carcinoma, macular degeneration, and men's health. Since 2016, Abe has been the owner of Associated Medical Writer Services where he writes and consults for clients in pharma and biotech. He has been a member of EMWA since 1996 and is a past-President (2017-2018) and workshop leader. He is currently the chair of the EMWA Ambassador's Programme.

PTF23 Subgroup Analysis

Profile: This workshop is targeted at medical writers who are aware of clinical studies, protocols, and clinical study reports.

Objective: The objective of this workshop is to understand the concept of subgroup analysis in clinical studies, and how to appropriately apply it to protocol and clinical study report writing. This workshop will also familiarise participants with the current European Medicines Agency (EMA) regulations on subgroups.

Content: This workshop will cover the importance of subgroup analysis, based on the current EMA regulations, and the associated limitations. This workshop will illustrate the implications of inappropriate emphasis on subgroup findings, the

implications of false-positives and false-negatives when making claims on the efficacy and safety of drugs, and discuss the considerations for protocol and clinical study report writing.

Cheryl Roberts

Cheryl is currently the head of the European medical writing group for BioMarin, and specialises in medical writing for serious and life-threatening rare diseases. She joined the pharmaceutical industry in 2001 in drug development, and continued in positions in medical editing and medical writing in both the pharmaceutical and consultancy industry. She holds a degree in Medical Biology and a Masters in Neuroscience.

PTF25a What Medical Writers Need to Know About Patient Registries

This workshop was previously run under the title 'Patient Registries as a Source of Medical Information'.

Profile: This workshop addresses medical writers who prepare publications based on the data from research databases, patient registries and other real-life data sources. Basic knowledge of the design of observational studies, epidemiological research and statistics is not critical, but would be beneficial.

Objective: To present the pros and cons of real-life research, to teach how to avoid over-interpretation of the study results, and to present these data effectively. Finally, to position patient registries as a complement to experimental studies.

Content: Nowadays, real-life medical data sources such as research databases or patient registries are gaining in importance as a source of medical information, and medical writers are often involved in preparing manuscripts based on these data. However, it should be highlighted that the way these data are reported differs from the way the data from experimental trials are presented. This workshop focuses on the basic concepts of real-life medical research, the differences between the data from real-life settings and experimental trials, the ways of publishing them, and the issues medical writer must think of while writing such papers. Furthermore, it will present the overview of the main aspects of analysis and interpretation of the registry data, including specific statistical problems (but without going into mathematical details). The workshop will include examples of registries and relevant papers to illustrate the potential of this kind of research.

Maria Kołtowska-Häggström

Maria is a co-owner of Proper Medical Writing, the first Polish medical writing agency, and an independent consultant, affiliated to the Department of Women's and Children's Health at Uppsala University, Uppsala, Sweden. In 1991, she began

working within the pharmaceutical industry where she gained experience in both the marketing and medical sides of the business. Between 2001 and 2013, Maria worked at Pharmacia (later Pfizer) in Stockholm, Sweden, where she was responsible for large research databases and patient registries. Maria led numerous research groups investigating growth hormone disorders based on real-life clinical data. She has an extensive track record of quality of life and patient-reported outcomes research. Furthermore, she lectured at different meetings related to late phase drug development and patient registries. She is a member of the European Medical Writers Association, European Association of Scientific Editors, European Society of Endocrinology, and Growth Hormone Research Society. She is also a reviewer for a number of peer-reviewed journals, an Associate Editor for *BMC Endocrine Disorders* and a section editor for *Medical Writing*.

Adam Jacobs

After getting bored of his first two careers (organic chemistry research and medical translating), Adam worked as a medical writer, first at a small contract research organisation and then at a large medical communications agency. He set up his own business in 1999, which was a lot of fun for a while but sadly didn't survive the recession and ceased trading in 2014. Adam was EMWA President in 2004–2005 and was co-author of EMWA's guidelines on the role of professional medical writers in publications. He finally got bored of medical writing as well, and now works as a statistician. However, he doubts he will ever get bored of coming to EMWA conferences.

PTF26 Medical Information: an Opportunity for Medical Writers

Profile: This workshop is designed to increase awareness and knowledge of Medical Information within the pharmaceutical industry, providing Medical Writers an alternative option in their Medical Writing career. Whilst no prerequisites workshops are required, participants are expected to have a basic understanding in drug development, dealing with US and EU regulations and medical education.

Objective: This workshop will provide participants an insight to how Medical Writers are contributing to Medical Information departments across the globe; including the creation and maintenance of medical standard responses, dealing with new data releases at congresses, and the overall distribution of Medical Content to key stakeholders. Participants will be able to evaluate how their existing writing skills can be transferred when creating medical content for healthcare professionals.

Content: The objectives will be achieved by providing an introduction to Medical Information, and the purpose of such departments existing in institutions whereby drug development occurs. Further, the workshop will consider the structure of

Medical Information – Global and Local markets – and the natural flow of medical content, touching on US and EU regulations. Much of the workshop will focus on medical content, and how multiple forms of communications are employed to educate customers on a particular product (medical standard responses, slide decks etc.) in a non-promotional manner.Simultaneously, the workshop will illustrate the role played by Medical Writers from writing responses to creating slide decks, as well as becoming specialists in a particular therapy area and/or products.

Rabiah Mirza

Rabiah is currently working for Synergy Medical, a medical communication agency managing projects and creating content for inflammation products. Previously, Rabiah was creating content for a digital specialist agency, PharmiWeb Solutions and prior to this, at Bristol-Myer Squibb within the cardiovascular therapy area. Having worked at the global level, it was vital to collaborate with local Medical Information teams, including US, EU and Australia. Regulatory Writing experience was obtained at PARXEL International and Chiltern International. Both her BSc. Biomedical Sciences and MSc. Clinical and Experimental Medicine were received at University College London.

PTF28 PowerPoint for Medical Writers

Profile: This workshop is aimed at medical writers looking to begin using Microsoft PowerPoint, or to refresh their basic skills.

Objective: The objective of the workshop is to give an overview of some of the functions of Microsoft PowerPoint, beginning from the very basics, and provide a practical guide to their use. There will be several hands-on exercises during the workshop for which a laptop with PowerPoint installed would be very helpful, although is not essential.

Content: The workshop will begin with the basics of creating a new slideshow, adjusting slide formatting and using master slides, and inserting text and graphics. We will then examine the use of graphs for optimal display of data, animations and how best to animate graphs to enhance the presentation of scientific data, and tips and tricks for efficient and tidy slide design.

Helen Chambers

Helen is the Global Head of Publications at Costello Medical Consulting, overseeing the publications work delivered by teams across the UK, US and Asia, as well as the personal and career development of the medical writers themselves. Her focus is on ensuring that projects are delivered to the highest possible quality and that the team are at the forefront of the latest industry developments, such as the development of digital content and patient engagement.

Helen became a Medical Writer in 2013 following a PhD and post-doctoral research in biochemistry at the University of Cambridge, and training as a Clinical Geneticist in an NHS lab. Helen holds the Certified Medical Publication Professional™ (CMPP™) credential from the International Society for Medical Publications Professionals (ISMPP), an Advanced Certificate in Medical Writing from EMWA, and serves as a member of the EMWA Professional Development Committee. She also delivers guest lectures on the University of Cambridge Therapeutic Sciences MPhil course on Medical Communication.

PTF3 Using Statistics in Medical Writing

Profile: Medical writers and editors with any level of experience who wish to learn more about the statistics they work with.

Objective: At the end of the course participants should understand the following:

- Populations to be analyzed: intent-to-treat, per-protocol, safety-evaluable, worst-case.
- Missing Data and Sensitivity Analyses
- Descriptive statistics: mean, median, mode, range, percentiles, box plot, normal and non-normal distributions, parametric and nonparametric tests, coefficient of variation
- Odds and Hazard Ratios
- Estimates and confidence intervals, and p-values
- Sample size calculations and what they mean

Content: We all write about statistics, but how many of us really have an intuitive feel for what we're writing about? This workshop is designed for participants who have little or no background in statistics. The following statistical concepts will be covered in depth: types of variables, levels of measurement, summary statistics, estimation and confidence intervals, and sample size calculations. Emphasis will be placed on understanding statistical presentations and reporting statistical information, not on calculations or mathematical explanations.

Barry Drees

Barry Drees was a witness to the start of the genetech madness when he got his PhD in molecular genetics at the University of California at San Francisco at the time of the founding of Genentech. Life's sense of irony took him to Germany, however, where he worked as a medical writer in the pharmaceutical industry for 12 years, setting up a Phase I writing group and leading several regulatory submission teams, among other activities. Barry is a frequent speaker on medical writing, statistics and other scientific communication topics for Management Forum Ltd, as well as various pharmaceutical associations. He also speaks on non-scientific topics such as the introductory presentation on the history of Malta at the 20th EMWA conference. He has appeared on an educational television programme in Germany to discuss the

ethics of genetic engineering and German radio to discuss medical writing as a career. He is the former Editor-in-chief of 'The Write Stuff', the Journal of EMWA (now called 'Medical Writing'), and is currently a Senior Partner at Trilogy Writing & Consulting. He served on the EMWA Professional Development Committee (EPDC) 2006-2009, with a focus on Train-the-Trainer events. Barry is a Nick Thompson Fellow of EMWA.

PTF30a Basics of Medical Statistics for Medical Writers Part 1

Profile: This workshop is aimed at medical writers who would like to improve their understanding of statistics. No previous knowledge of statistics is assumed, but a basic familiarity with what clinical trials are (eg experience with writing CSRs or publications of clinical trial results) would be helpful. Please note that this workshop is at a basic level and medical writers who are already experienced and confident in writing about statistical techniques may not benefit from it.

Objective: To help medical writers to understand the basic principles behind statistical analysis as used in clinical research (both in clinical trials and epidemiological research).

Content:

- Types of data
- The normal distribution and other distributions
- Hypothesis testing and P-values
- Estimation and confidence intervals
- Measures of variability: standard deviations and standard errors
- Some common statistical tests
- Parametric and non-parametric tests

The workshop will focus on what medical writers need to know about statistics to be able to present them in reports and publications, and not on mathematical details.

This workshop is aimed at making sure medical writers who are not experienced with using statistics have a good understanding of the basics. The companion workshop "Basics of medical statistics for medical writers part 2" will cover some more advanced concepts.

Adam Jacobs

After getting bored of his first two careers (organic chemistry research and medical translating), Adam worked as a medical writer, first at a small contract research organisation and then at a large medical communications agency. He set up his own business in 1999, which was a lot of fun for a while but sadly didn't survive the recession and ceased trading in 2014. Adam was EMWA President in 2004–2005 and

was co-author of EMWA's guidelines on the role of professional medical writers in publications. He finally got bored of medical writing as well, and now works as a statistician. However, he doubts he will ever get bored of coming to EMWA conferences.

PTF4 Medical Writing and Quality Control: Clinical Study Reports

Profile: The workshop is aimed towards medical writers at all levels of experience, and whether working in a freelance capacity, or within a CRO environment, or for a pharmaceutical company. It will be an ideal forum for those who either have no quality control (QC) system in place, or are looking to develop one, whilst those with experience of working with, or implementing QC systems will be able to explore and share best practice. It is not necessary to have attended any other workshops.

Objective: For a medical writer the correct application of a QC process minimises errors in the factual presentation of data, rectifies spelling mistakes and ensures accurate document structure. At the end of the workshop, participants should have an understanding of why it is important to have a QC procedure in place for written documents including clinical study reports, when in the writing process QC should be implemented, and how to document the results.

Content: The importance of QC in medical writing will be covered. The consequences of not implementing and following a QC process will be discussed. QC requirements, who should perform the task, and how to carry it out will all be addressed. The workshop is designed to both inform and share experiences; therefore interaction of participants will be actively encouraged. Although the workshop is applicable to other types of medical writing it will primarily use clinical study reports as working examples.

Alison McIntosh

Alison has been a medical writer for the pharmaceutical industry for almost 30 years, and has written extensively for regulatory authorities, and other audiences. She became a medical writer after completing her PhD and a further 5 years of postdoctoral research in molecular virology. Her wealth of experience encompasses many different types of documents including manuscripts, book chapters, and clinical and scientific abstracts, as well as clinical study reports, investigator brochures and other regulatory documents. Alison has been a workshop leader since 2001 and is a section editor for the EMWA journal Medical Writing as well as a member of the EMWA Special Interest Group on regulatory public disclosure. She also serves as a committee member of the EMWA CORE Reference Project.

PTF40 Statistical Testing

Profile: This workshop is for participants who wish to develop or refresh their understanding of how basic statistical testing procedures work.
Participants should:

- be familiar with basic arithmetic, including squares and square roots
- bring a calculator or smartphone app capable of square and square root functions
- come prepared to engage in exercises and discussions

Objective: Non-statisticians often see statistical testing as a black box, into which statisticians pour numbers, to make p-values for medical writers to report. The underlying mathematics can appear intimidating, so this workshop breaks down the elements of some basic statistical tests, to illustrate how they work and what factors influence the results. Participants will gain a greater appreciation of how the outputs of statistical tests are generated, and what real-world decisions influence the likelihood of a significant outcome. This understanding will support their work when reporting statistical results.
This is a highly interactive workshop which includes four group exercises.

Content:
This workshop addresses the following areas:

- Why we need statistical tests
- Populations and samples
- Continuous and categorical variables
- Describing continuous data
- Normal distribution
- Hypothesis testing
- Test on continuous data (Student's t)
- Confidence intervals
- Test on categorical data (chi-square)
- Statistical significance and clinical relevance
- Type II errors (sample sizes)
- Data errors, recall bias, multiple testing

Participants should note that this workshop focuses in depth on statistical testing. The concepts of mean, standard deviation, and the normal distribution are covered briefly as these are essential to the working of many tests. Participants seeking more in-depth coverage of mean, standard deviation, normal distribution, and other fundamental issues should also consider taking workshop PTF30a.

James Visanji

James holds a PhD in Medicine from the University of Manchester, Masters in Clinical Genetics from the University of Sheffield, Chartered Linguist status from the Chartered Institute of Linguists, and the European Medical Writers Association Nick Thompson Fellowship.
After postdoctoral work at Istituto Europeo di Oncologia, James started his medical writing career in 2006. Based in Frankfurt, he is currently Associate Director of

Clinical Writing at Certara Insight, and was previously Medical Writing Manager at Trilogy Writing, and Deputy Director at Accovion (now Clinipace).
James focuses on clinical and regulatory documentation, in particular, submission dossiers and subsequent regulatory interactions. James has been training medical writers and physicians since 2012, and claims to get his biggest buzz from making the next generation of writers as effective as possible, as quickly as possible.

PTF41 Basics of Medical Statistics for Medical Writers Part 2

Profile: This workshop is aimed at medical writers who would like to improve their understanding of statistics. Prior attendance at "Basics of medical statistics for medical writers part 1" is not required; however, it is assumed that participants are already familiar with basic statistical concepts such as P values and estimation. Anyone who is not confident in their understanding of such concepts is encouraged to attend "Basics of medical statistics for medical writers part 1" before taking this workshop.

Objective: To help medical writers to understand the some of the statistical techniques used in clinical research (both in clinical trials and epidemiological research).

Content:

- Brief review of the basics: P values, confidence intervals etc
- Regression analysis
- Intent to treat and per protocol analyses
- Missing data
- Interim analyses
- Primary and secondary analyses

The workshop will focus on what medical writers need to know about statistics to be able to present them in reports and publications, and not on mathematical details.

Please note that there is some overlap between this workshop and workshop PTF40, "Statistical testing". However, anyone interested in learning more about statistics should not be afraid of attending both workshops, as the material will be presented in different ways, which can often be a helpful way of consolidating learning.

Adam Jacobs

After getting bored of his first two careers (organic chemistry research and medical translating), Adam worked as a medical writer, first at a small contract research organisation and then at a large medical communications agency. He set up his own business in 1999, which was a lot of fun for a while but sadly didn't survive the

recession and ceased trading in 2014. Adam was EMWA President in 2004–2005 and was co-author of EMWA's guidelines on the role of professional medical writers in publications. He finally got bored of medical writing as well, and now works as a statistician. However, he doubts he will ever get bored of coming to EMWA conferences.

PTF42 Essentials of Data Visualisation

Profile: Medical writers with 0-4 years of experience. No prior knowledge in visual communication is required.

Objective: To learn basic guidelines to achieve appropriate graphical representations of data which retain the main message and improve visual appeal. At the end of the course, participants should be able to: Understand the principles of data visualization; Identify a main message for each graphical representation; Select an appropriate graphical representation for each type of data and purpose; Improve clarity of the chart or table.

Content: Medical writers need to present data clearly and accurately. Visual representations of data allow to communicate information faster and easier to all audiences. Tables and charts are the most direct data visualization tools. However, if done inappropriately they can mislead the audience and convey the wrong information. We will introduce participants to the basic principles of design and fundamentals of visualization, and discuss applications and requirements of the most used graphical representations in medical writing – charts and tables. We will cover the choice of a "main message" for each image, and formatting issues that may mislead the reader. Examples and practical group activities are included, as well as specific tips to achieve clear visuals focused on the data. Although some topics of the workshop may partially overlap those presented in PTF1, this course is more oriented towards fundamentals of design and visualization.

Ana Goios

Based in Portugal, Ana Goios works remotely as a medical writer for P95 Epidemiology and Pharmacovigilance. In her daily work, she prepares reports, systematic reviews and other manuscripts, posters and presentations, often featuring visualizations. Ana holds a PhD in Genetics and has worked in academic research in Genetics and in Population Health for more than 15 years. In parallel, she completed two Scientific Illustration courses, a post-graduation course on Biostatistics in Health Sciences, and has engaged in self-training in data visualization and design. Ana is an EMWA member since 2018 and has since then attended EMWA Professional Development Program Workshops and obtained the EPDP Foundation Certificate. Her multidisciplinary background allows her to produce complete medical communication documents using data analysis tools and producing graphics, illustrations and texts.

EUROPEAN MEDICAL WRITERS ASSOCIATION

PTF5a Medical Writing and Quality Control of Documents Entering the Public Domain: Manuscripts and Abstracts

Profile: The workshop is particularly suited to medical writers who are writing documents entering the public domain. It will be most useful for those who either have no quality control (QC) system in place, or are now looking to develop one. For medical writers with greater experience it will provide a forum for discussion and sharing best practice. The workshop content is relevant to those working in a freelance capacity, as well as medical writers employed by CROs, communications agencies, or pharmaceutical companies.

Objective: For a medical writer with documents destined to enter the public domain a QC process is essential. A properly implemented QC process helps reduce errors in the factual presentation of data, and when writing a manuscript ensures an accurate document structure is followed to fulfil a journal's specific requirements. The workshop will focus on developing a QC process for non-regulatory documents, particularly manuscripts, and detail several strategies to achieve this.

Content: The importance of applying a QC process to documents entering the public domain will be discussed. Methods of implementing the QC process will be outlined and several examples worked through in detail. Although the workshop is applicable to other types of medical writing it will primarily use manuscripts and abstracts as working examples. Regulatory documents (e.g. clinical study reports) will not be covered.

Phil Leventhal

Phil is a Principal Medical Writer at Evidera, where he specializes in publication writing. He has more than 15 years of experience as a medical writer, has written more than 100 peer-reviewed publications. Phil has been the Editor-in-Chief of Medical Writing and on EMWA's Executive Committee since 2011, and he leads professional workshops and academic workshops on writing peer-reviewed publications throughout Europe and North America.

Stephen Gilliver

Stephen (Steve) Gilliver has been an EMWA member for 9 years and is Co-Editor of Medical Writing. He has spent the best part of a decade working as a science editor and more recently a medical writer. Having moved from his native UK to Sweden in 2010, he ultimately settled in Malmö, where he now works home-based. He is a joint British-Swedish citizen and speaks fluent Swedish.

EUROPEAN MEDICAL WRITERS ASSOCIATION

PTF8 Cross-Cultural Communication

Profile: Anyone who wishes to explore how to recognise a cultural issue or problem (particularly in a medical writing setting) and how to approach it wisely. Curiosity and willingness to share own experiences are the most important prerequisites.

Objective: By raising awareness about cultural differences and key factors involved in intercultural communication, this workshop aims at giving participants an increased ability to recognise cultural issues in situations that medical writers frequently encounter, and the basic skills needed to avoid potential problems.

Content: The ability to operate effectively in multicultural contexts has become a key business skill. Medical writers often work in international teams and many of us have experienced different working styles and ways of communicating that can create a host of problems. Knowledge about cultural characteristics and differences, and how they affect medical writing can diminish these problems. The workshop will be a mixture of lecturing, discussions and group work. The most common ways of distinguishing cultures from each other (national and organisational) will be covered and the pre-workshop assignment (the Enneagram's nine personality types) will help to raise awareness about one's own personal inclination to meet an unknown culture. Discussion groups will be put together from information given in the pre-workshop assignment.

Kari Skinningsrud

Kari is an experienced freelance medical writer who works mainly with medical communication and training, particularly manuscript writing. She has given workshops on manuscript writing at several universities in different countries, gives EMWA workshops on manuscript writing, grant-writing and cross-cultural communication, and currently serves on EMWA's Professional Development Committee (since 2013). During 2004–09 she was a member of EMWA's Executive Committee. She is bilingual Canadian/Norwegian, has a MSc in biochemistry, has worked for more than 10 years in clinical development in pharmaceutical industry, and is currently a regular writing consultant for a medical device company.