EUROPEAN MEDICAL WRITERS ASSOCIATION

EMWA Professional Development Programme Brochure

(Last Updated: August 2026)

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.

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. 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. 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.
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 Good Pharmacovigilance Practice (GVP) Module VII and ICH E2C. There will be particular emphasis on 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.

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.

DDA1(a,b) 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

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.

Claire Dyer

Claire is a Senior Director of Global Submissions at Veristat. 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 worked as a MW Manager at Trilogy and ICON before joining Certara and now Veristat as one of the Submission Leads. 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 according to the RMP guidance and template (GVP Module V). 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 RMP format.

Content: This workshop will provide an overview of the 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 GVP Module V will be provided. Major challenges will be explored in exercises. Particular emphasis will be given to the definition of important risks, pharmacovigilance activities and risk minimization measures.

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.

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.

Mona Wegert

Mona is an Expert Medical Writer at Boehringer Ingelheim with more than 10 years of experience in regulatory medical writing across the drug development lifecycle. She has extensive experience in oncology, supporting programmes from early clinical development through to late-stage development and regulatory submissions. For several years, Mona has been co-responsible for the clinical study report (CSR) process, giving her a practical perspective on both the strategic and operational aspects of CSR development. In addition to her regulatory writing expertise, she is passionate about knowledge sharing and has mentored and trained numerous medical writers throughout her career.
Mona holds a degree in Human Biology and earned her PhD in Immunology before moving into medical writing.

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 DDA14, 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.

Content: 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
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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.

DDA27 Medical Writing for Biosimilars

Profile: This workshop is designed for Medical Writers with foundational experience in drug development, including a working knowledge of basic pharmacokinetics and statistics. Participants should have hands-on experience with clinical study reports and regulatory submission dossiers. Whether you are early in your career or a seasoned professional looking to expand your knowledge, this is an opportunity to learn about the regulatory and scientific evolution of biosimilars from a Medical Writer's perspective.

Objective: Biosimilars represent a dynamic and rapidly evolving area in pharmaceutical development. By the end of this workshop, participants will be able to:

- Articulate the key differences between biosimilar and new biological entity development, and understand how these distinctions shape the development of clinical documents
- Apply biosimilar-specific considerations when writing and reviewing clinical study reports for Phase I and Phase III studies
- Navigate the unique regulatory and scientific challenges encountered when preparing clinical documents for a biosimilar submission dossier to support high-quality Medical Writing in biosimilar programs

Content:

- Overview of biosimilar clinical development: regulatory landscape,

comparability exercise, and development paradigm
- Writing clinical study reports for biosimilar Phase I (PK/PD, immunogenicity) and Phase III (confirmatory efficacy and safety) studies
- Preparing the clinical documents of a biosimilar regulatory submission dossier

Sabrina Stöhr

Sabrina is a Regulatory Medical Writer with 10+ years of experience combining deep scientific credibility, strong regulatory judgment, and a pragmatic approach to delivering high-quality documentation across all stages of clinical development. She has led and authored a broad range of regulatory documents across multiple indications, including oncology, inflammatory diseases, and biosimilars, with particular strength in Clinical Study Protocols and Reports, Briefing Documents, and Clinical Summaries and Overviews.
Her scientific foundation includes a PhD in human genetics, a postdoc in cancer research, and a Master's in Drug Regulatory Affairs, giving her a strong ability to connect scientific evidence with regulatory expectations and to critically assess study design and data interpretation. In addition to her writing expertise, Sabrina is an experienced workshop leader who translates complex regulatory concepts into practical guidance, combining scientific rigor with pragmatic project management to strengthen team performance and regulatory readiness.

Katharina Brauburger

With over 10 years of experience in regulatory Medical Writing, Katharina has developed broad expertise across all stages of clinical development and a wide range of therapeutic areas. She has a strong track record of writing and managing complex regulatory documents for both biosimilar and innovative medicine programs, including the full range of documents required for successful regulatory submissions, from briefing documents to clinical overviews.
Her career across several pharmaceutical companies has given her a thorough understanding of the scientific, regulatory, and operational landscapes, and the challenges of both biosimilar and innovative medicine development on Medical Writing deliverables. As a biologist by training and with her doctoral research background in molecular tumour biology, Katharina brings a strong scientific foundation that enables her to understand and communicate the complexities of clinical drug development.
An experienced trainer, Katharina combines scientific and regulatory expertise with a practical, experience-driven perspective.

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

Carola Krause is an Associated Principal Medical Writer at Trilogy Writing & Consulting, focusing on non-clinical and clinical regulatory writing. Based in Potsdam, Germany, she has a postdoctoral background in molecular stem cell biology and extensive hands-on experience in academic and pharmaceutical research, project management, and all stages of drug development.

As a long-term EMWA member, Carola has contributed to its educational program, founded and chaired the Creative Team and the Sustainability Special Interest Group, and served as EMWA's President (2020–2022). She continues to represent EMWA as an ambassador and AI liaison for the Visual Communications Special Interest Group.

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. There is an emphasis on the new opportunities to design studies using existing clinical databases and target trial emulations (TTE). 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. A glimpse into additional ways to analyze databases. 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 across all therapeutic areas.

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 35 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 Executive Director, Head of Global Medical Writing, 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.

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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 combining deep scientific credibility, strong regulatory judgment, and a pragmatic approach to delivering high-quality documentation across all stages of clinical development. She has led and authored a broad range of regulatory documents across multiple indications, including oncology, inflammatory diseases, and biosimilars, with particular strength in Clinical Study Protocols and Reports, Briefing Documents, and Clinical Summaries and Overviews.
Her scientific foundation includes a PhD in human genetics, a postdoc in cancer research, and a Master's in Drug Regulatory Affairs, giving her a strong ability to connect scientific evidence with regulatory expectations and to critically assess study design and data interpretation. In addition to her writing expertise, Sabrina is an experienced workshop leader who translates complex regulatory concepts into practical guidance, combining scientific rigor with pragmatic project management to strengthen team performance and regulatory readiness.

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.

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 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, and AI prompts to assist with drafting and review.

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.

Cornelia Weiss-Haljiti

Expert Medial Writer, Lay Language & New Media

Cornelia leads the Informed Consent activities of the Lay Language & New Media medical writing team at Boehringer Ingelheim Pharma GmbH & Co.KG. She loves turning dense scientific ideas in clear, engaging language refining the methods that help others to do so. She holds the Plain Language Certificate from Simon Fraser University.

Her path into plain language began when she designed a digital platform to share lay summaries of study results with the public. Before that, she had created templates for lay summaries and written regulatory documents across all phases and therapeutic areas for many years.

At heart, Cornelia is a researcher. As a biochemist with a PhD in endothelial cell biology, she spent more than a decade leading projects and laboratories in academia, biotech, and the pharmaceutical industry. She remains inspired by seeing

early discoveries in targets, drugs, and biomarkers progress into clinical development.

DDA36 Non-clinical Elements of the eCTD

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 non-clinical and clinical development process. Preference is that participant also have had some experience of writing either non-clinical study reports or taken the EMWA course on non-clinical study reports.

Objective: • To introduce participants to the preparation of 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
Non-clinical summaries can often be challenging due to the number of studies to be presented and the nature for the studies utilising methods that the MW may not be familiar with.

Content: The workshop will provide an overview of the structure of the nonclinical elements of the CTD and place in the context with the other clinical and CMC elements. The workshop will aim to introduce the type and nature of non-clinical data and the relevant placement of the studies in to the respective 2.6 sections. The workshop will detail the structure and format of the Module 2.4 with best practices from the guidelines and from examples.

Claire Dyer

Claire is a Senior Director of Global Submissions at Veristat. 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 worked as a MW Manager at Trilogy and ICON before joining Certara as one of the Submission Leads. She has a wide range of experience and a particular interest in regulatory documents covering various therapeutic areas.

Kelly Smith

Kelly is a Senior Director of Global Submissions at Veristat and has over 20 years of industry experience as a Regulatory Medical Writer. After her PhD in Biomedical Sciences, Kelly transitioned into Regulatory Medical Writing and has worked her entire career at specialist medical writing service providers, working with many

different clients from small to large pharmaceutical companies across multiple therapeutic areas. During her career, Kelly has led a wide range of medical writing projects, encompassing submission-level, study-level and drug safety documents, and works on both non-clinical and clinical documents. Kelly has been responsible for training numerous medical writers during her career and, in her current role as one of the Submission Leads at Veristat, she continues to author documents, but also advises clients on best practices for writing high-quality submission-ready regulatory 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.

Debbie Jordan

Debbie has been working in the pharmaceutical industry for over 35 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.

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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.

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.

DDF17a Ethical Issues in Clinical Trials and Health Care

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.

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

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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.

EUROPEAN MEDICAL WRITERS ASSOCIATION

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 (PhD in Biology) has been a regulatory MW for >20 years, covering both pharmaceuticals and medical devices. Her core competencies include clinical trials and submissions documents, data disclosure and protection, and project and people management. Over the years, she took on a wide range of industry positions, as freelancer, as employed regulatory writer, and as head of medical writing departments in the CRO and big pharma settings. She currently leads the MW pediatrics Immunology portfolio at Johnson & Johnson Innovative Medicine. Raquel is an active EMWA member since 2006, serving in various roles, is currently Editor-in-Chief of Medical Writing and member of the EMWA Executive Committee.

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.

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, was Treasurer of EMWA from 2005–2009, and has been Co-Treasurer with Julia Cooper since autumn 2024.

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).

DDF23 (a) 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, was Treasurer of EMWA from 2005–2009, and has been Co-Treasurer with Julia Cooper since autumn 2024.

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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

DDF2b Writing an Investigators 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.

Shreya Bhargava

Shreya stumbled upon the field of Medical Writing soon after completing her Masters in Biotechnology in 2014. Ever since, she has found herself curiously involved with the craft. Over the years, Shreya has worked on a variety of clinical regulatory documents across therapeutic areas and development phases.
Shreya has worked across diverse ecosystems, including business service providers, a contract research organization, and big pharma, and brings with her a repertoire of experience and insight in the world of medical writing.
Shreya has been a presenter at the DIA India Conference (2017) and was a presenter and member of the scientific committee for the annual conference held by the Indian Society for Clinical Research (2019).

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 requirements. 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 information 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 (a,b) 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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where she was Vice President/President in 2017-2019; she has been chairing the 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.

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.

DDF33+34 (a,b,c,d) 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

Arine Kassabian

Arine is a senior medical writer at Veristat. She has a PhD in sports sciences and has worked in academic research. She has been a medical writer since 2021 and is experienced at writing a wide range of regulatory documents on pharmaceuticals and medical devices, covering various therapeutic areas. Arine has also mentored

medical writers on several types of documents.

Gaele Ducher

Gaele is a Medical Writing Manager at Veristat. 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.

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 (PhD in Biology) has been a regulatory MW for >20 years, covering both pharmaceuticals and medical devices. Her core competencies include clinical trials and submissions documents, data disclosure and protection, and project and people management. Over the years, she took on a wide range of industry positions, as freelancer, as employed regulatory writer, and as head of medical writing departments in the CRO and big pharma settings. She currently leads the MW pediatrics Immunology portfolio at Johnson & Johnson Innovative Medicine. Raquel is an active EMWA member since 2006, serving in various roles, is currently Editor-in-Chief of Medical Writing and member of the EMWA Executive Committee.

DDF38 (a) 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.

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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.

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 35 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 An Introduction to Informed Consent forms

Profile: This workshop is aimed at all medical writers 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: This workshop will start with a discussion about the consent process for clinical trials, including real-life examples. Detail will be provided on the suggested content of patient information leaflets, covering current global regulatory guidance and sources of supporting information. Important considerations when writing for clinical trial participants will be highlighted. Workshop exercises will be used to practice modifying typical source information into a format suitable for inclusion in a patient information leaflet.

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, was Treasurer of EMWA from 2005–2009, and has

been Co-Treasurer with Julia Cooper since autumn 2024.

Stephen Moore

Stephen started working as a Medical Writer in 2012, after completing a PhD in Chemistry at the University of Southampton. His first role comprised a mixture of medical affairs and publications work within a Medical Communications Agency. He later switched to regulatory writing within a large Contract Research Organization. In his current role, as a Principal Medical Writer at Effective Medical, Stephen writes and reviews a broad range of regulatory documents, including informed consent materials, covering a variety of indications and trial phases.

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.
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, was Treasurer of EMWA from 2005–2009, and has been Co-Treasurer with Julia Cooper since autumn 2024.

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.

EUROPEAN MEDICAL WRITERS ASSOCIATION

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 (PhD in Biology) has been a regulatory MW for >20 years, covering both pharmaceuticals and medical devices. Her core competencies include clinical trials and submissions documents, data disclosure and protection, and project and people management. Over the years, she took on a wide range of industry positions, as freelancer, as employed regulatory writer, and as head of medical writing departments in the CRO and big pharma settings. She currently leads the MW pediatrics Immunology portfolio at Johnson & Johnson Innovative Medicine. Raquel is an active EMWA member since 2006, serving in various roles, is currently Editor-in-Chief of Medical Writing and member of the EMWA Executive Committee.

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

Carola Krause is an Associated Principal Medical Writer at Trilogy Writing & Consulting, focusing on non-clinical and clinical regulatory writing. Based in Potsdam, Germany, she has a postdoctoral background in molecular stem cell biology and extensive hands-on experience in academic and pharmaceutical research, project management, and all stages of drug development.

As a long-term EMWA member, Carola has contributed to its educational program, founded and chaired the Creative Team and the Sustainability Special Interest Group, and served as EMWA's President (2020–2022). She continues to represent EMWA as an ambassador and AI liaison for the Visual Communications Special Interest Group.

Sally Hill

Sally is based in the Netherlands where she works as Associate Director Scientific Communication at a 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 move into the pharmaceutical industry gave 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 served as Chair of SENSE, the Society of English language professionals in the Netherlands.

DDF55 - Converting an Investigational New Drug (IND) application into an Investigational Medicinal Product Dossier (IMPD): process, regulatory requirements and potential pitfalls

Profile: This course is intended for medical writers with some experience in regulatory writing and already familiar with the drug development process

Objective: Participants of this workshop will get familiar with the differences and similarities between the IND and IMPD and will be equipped for preparing a full IMPD document using IND as a source and starting point.

EUROPEAN MEDICAL WRITERS ASSOCIATION

DDF57 All Clinical trials in Europe at your fingertips: Introduction to the public portal of the Clinical Trial Information System (CTIS)

Profile: The workshop is for anybody who is interested to learn about the key functionalities of the CTIS public portal. This may be for his or her own benefit as a potential trial participant, as a patient advocate, a medical affairs professional interested in competitor activities, a medical writer who wants to see how other companies approach the provision of key information on clinical trials, a transparency and disclosure professional evaluating results postings both in the scientific and lay summary by other companies. A basic understanding of clinical research is helpful, eg about clinical phases, indications, the relevance of inclusion and exclusion criteria. Ideally participants are familiar with the key documents in a clinical trial, ie the study protocol, informed consent form, etc. People with some knowledge about the way information is entered in CTIS may benefit a lot too. 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: Knowing about this important source is important for regulatory medical writers, medical affairs associates, writers and other professionals working in the realm of disclosure, and quality assurance specialists. The public portal offers highly structured, reliable and approved information about clinical trials in Europe. Participants will learn about the key features of CTIS, the way the public portal can be searched for various items including key trial documents. In addition, the clinical trials map in Europe will be introduced and demonstrated. Participants will learn to optimally display their searches and to download documents. They will also get an idea about the limitations of the CTIS public portal.

Content: The workshop will consist of a short introduction into CTIS which will also include key terminology. Also the CTIS transparency rules will briefly be presented and discussed. Thereafter the key search functionalities will be introduced, findings trials in certain indications, from certain companies, developmental stages. How to search and download key documents will be shown. Then participants will experiment themselves with the system following some leads provided by the workshop leader. The last 30 minutes will be for Q&A around CTIS and its public portal.

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 meanwhile gained some 30 years of experience in both medical communication and regulatory medical writing focussing

on the preparation of clinical documents needed for marketing authorization applications in all relevant geographies across therapeutic areas. He founded and established the medical writing function at Boehringer Ingelheim Pharma and headed the Innovation Medical Writing Group focussing on lay communication, good graphics development, video creation and AI-driven writing at Boehringer Ingelheim Pharma. He was a member of the TransCelerate "Return of Results" work stream, is contributing to the Good Lay Summary Practice initiative and was co-author on PFMD Plain Language Summary guidance for scientific articles. Thereafter, he assumed the role of Director Global Regulatory Affairs in BioNTech serving as CTIS (Clinical Trial Information System) Lead supporting all aspects of clinical trial authorizations in EU and EEA. He has lately started his own consultancy "RSW – RegulatoryScienceWriting" providing support on medical writing and regulatory topics.

DDF59 Inclusion by Design: Preparing Medical Writers to Address Diversity in Clinical Trials

Profile: "Inclusion by Design: Preparing Medical Writers to Address Diversity in Clinical Trials" Workshop can benefit medical writers to gain valuable skills in addressing diversity in clinical trial design, patient recruitment, and data reporting.The workshop is intended for medical writers with little or no experience of diversity and inclusion in clinical trials, although relevant experience in key regulatory documents like clinical trial protocols and clinical study reports is recommended. No prerequisites for this workshop.

Objective: The objectives of this workshop include:

- Enhanced Knowledge of Diversity Goals
- Developing Diversity-Focused Documents (Protocols)
- Clarity in Response
- Increased Awareness of Bias
- Improved Patient Recruitment Strategies

On completion of this workshop, the participants should be confident about ensuring diversity and inclusion in documents prepared for health authority submissions and lead teams in meaningful discussions about inclusive clinical trials.

Content: Difference between diversity and inclusivity

- Background and history
- Why diversity matters
- Overview of Agency initiatives – FDA, EMA, and MHRA
- Ethical considerations – presentation on ethics in diverse clinical trials
- Group discussion on ethical challenges
- Detailed overview of the FDA's diversity plan
- Role of medical writers in addressing diversity

- Group writing activities
- Best practices for designing inclusive clinical trials
- Recruitment and retention strategy for diverse populations
- Elements of a Diversity Plan
- AI to address diversity and inclusivity in clinical trials

This workshop will include presentations and group writing exercises and will follow an interactive approach.

Shrutika Rogye

Shrutika brings over 15 years of experience in the medical writing industry. After earning her master's degree in clinical research, she discovered her passion for preparing regulatory submission documents and has excelled in this area since 2010. Currently she leads the development of complex regulatory submission documents, oversees project management, and provides training for medical writing associates. In addition, she has gained valuable experience working with various CROs and pharmaceutical companies. Through this workshop, she aims to share the expertise she has cultivated over the years.

Bhawna Basin

Bhawna Basin brings over 15 years of experience in clinical development and scientific research across a broad range of therapeutic areas. With a background in pharmacy and clinical research, Bhawna began her career in academia, where she spent three years before transitioning to the pharmaceutical industry, specifically in drug regulatory affairs. In 2013, she moved to Germany and changed careers to become a medical writer. Over the past 11 years, she has developed a deep passion for medical writing. While she is not a clinician, she finds fulfilment in contributing to patient care by writing clear, concise documents that facilitate faster approvals.

DDF60 The Lean Approach: From Protocol to Submission

Profile: The participants should have a basic understanding of the drug development process and its clinical documents such as CSPs, CSRs, summaries and overviews, and how they relate to each other.

Objective: Participants will gain insight into lean medical writing across the chain of documents, from clinical study protocols through to final submission dossiers, and how it aligns with regulatory expectations.

Content: Lean writing techniques: The principles of lean writing and its application in medical writing will be presented. We will utilize applicable templates (e.g. the TransCelerate CSP/CSR) with practical examples and case studies to illustrate the benefits and impact on regulatory compliance.
Efficient cross-referencing and redundancy mitigation: We will explore effective cross-referencing techniques across clinical documents within the specified scope. Our focus will be on minimizing redundancies, reducing the number of appendices,

and consequently reducing document size.
Reviewer and regulatory emphasis: Participants will learn to focus on the essential information required for approval, while avoiding unnecessary details. Strategies for managing an excess of (exploratory) analyses will also be discussed.
Expanding lean writing opportunities: We will introduce opportunities for employing deductive medical writing in CSRs and Module 2 documents, emphasizing result interpretation over descriptive writing, and providing practical strategies for implementation.

Suvi Rajamaki

With several years of medical writing and academic research experience, Suvi brings a wealth of knowledge and experience in authoring different document types, both in regulatory and scientific areas. Suvi has a Ph.D. in synthetic organic chemistry, and in nanotechnology and functional materials. Her medical writing experience includes developing and authoring clinical study protocols, study reports and summaries of clinical efficacy and safety for INDs /NDAs /MAAs. She has extensive therapeutic experience across multiple areas.

Iris Bresink

With over 25 years of clinical development experience, including more than 20 years in medical writing and 5 years in regulatory affairs, Iris brings a wealth of knowledge and experience. Iris is an authorized pharmacist with a Ph.D. in pharmacology. Her medical writing experience includes developing and authoring clinical overviews, summaries of clinical efficacy and safety for NDAs/BLAs/MAAs, as well as life cycle management and various regulatory documents. She has extensive therapeutic experience across multiple areas. In recent years, Iris has played a key role in developing standards within the Medical Writing area of a larger pharmaceutical company and providing training for medical writers, particularly in strategic and regulatory writing. In 2024, Iris decided to start her own medical and regulatory writing business.

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.

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.

Johanna Chester

Johanna Chester is a medical and scientific communications consultant. She has co-authored over 80 publications in indexed journals in various disciplines, including surgery, dermatology, nephrology, urology, haematology, biomedical sciences and laboratory medicine. She teaches medical writing to doctors and aspiring medical writers in Italy. Johanna actively supports EMWA initiatives, as a member of the Executive Committee, EPDC, and the Italian LEG.

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.

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.

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 Finance Committee and also provides a workshop: 'Oral presentations: skills to help you survive or even shine'. 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.

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, was Treasurer of EMWA from 2005–2009, and has been Co-Treasurer with Julia Cooper since autumn 2024.

LWF22 Inclusive Language in Medical Writing: How are our words perceived when we communicate?

Profile: This workshop is aimed at improving the inclusive language sensitivity of medical writers. Previous attendance at another workshop is not required.

Objective: Why should equality be a priority for all of us? Genuine intentions are essential to tackle diversity—when the purpose is not genuine, one ends up with little more than tokenism or empty words.
Equality and inclusive language go hand in hand. Inclusive language is complex and seeks to embrace diversity and treat all people with respect, dignity, and impartiality. What is more complex than diversity?
What nuances of inclusive communication should medical writers be aware of when drafting texts, and how to advocate for inclusive language among our peers and stakeholders?
This workshop will help you develop an eye for non-inclusive wording and provide tips and tricks to avoid non-inclusive and ableist language.

Content:

- What is inclusive language?
- Why is it important?
- What do regulations say about it?
- Key considerations when writing an inclusive text
- The impact Medical Writers have when using inclusive language
- Language processing models. Can AI-based tools help us in writing inclusive texts?

Laura C. Collada Ali

Currently working as a Senior Medical Writing Manager at Trilogy Writing & Consulting, she has over 25 years of experience in writing, editing, and managing medical and scientific documentation for diverse clients and audiences. Laura is EMWA-certified and holds multiple certificates in linguistics, pharmacology, medical devices, and clinical research. She has served EMWA in different roles: Professional Education Committee member and chair, as well as a member of the Executive Committee.

Heather Mason

Heather worked in both clinical operations and medical affairs departments for eight years before turning to medical writing in 2010. She has been a freelance writer since 2018, working in a wide range of therapeutic areas for pharma, biotech, not-for-profit, and patient organisations. Her specialist area of interest is rare diseases, and she writes predominantly in medical communications, ranging from conference coverage and manuscripts to patient-focused materials and whole project management. Since working on rare diseases and having a son with a disability, she has a passion for patient advocacy, understanding first-hand how non-inclusivity can adversely affect the day-to-day lives of people.

MCA28 Publication Planning

Profile: This workshop is aimed at experienced writers who are interested in or work in publication planning and strategic communication. It is particularly useful for writers who are expected to develop and/or manage 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. authorship, 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, authors and approval management, and milestone dates. The most relevant aspects of an effective communication strategy and its implementation will be actively discussed and practiced.

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, leads EMWA's Salary Survey team, 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.

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, was Treasurer of EMWA from 2005–2009, and has been Co-Treasurer with Julia Cooper since autumn 2024.

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, the appropriate use of graphics and the presentation of numeric values 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, GLSP (Good Lay Summary Practice Initiative [EudraLex 10]) will be introduced and briefly discussed. The content requirements for lay summaries will be introduced and different approaches will be presented discussed. The basics of plain language writing will be covered along with relevant guidance documents (GLSP, ISO Norm on Plain Language 24495). Also, the appropriate use of graphics and pictograms will be presented and discussed. 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. We will also look at the latest developments in the field of lay summaries and similar documents such as the Lay Protocol Synopsis.

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 meanwhile gained some 30 years of experience in both medical communication and regulatory medical writing focussing on the preparation of clinical documents needed for marketing authorization applications in all relevant geographies across therapeutic areas. He founded and established the medical writing function at Boehringer Ingelheim Pharma and headed the Innovation Medical Writing Group focussing on lay communication, good graphics development, video creation and AI-driven writing at Boehringer Ingelheim Pharma. He was a member of the TransCelerate "Return of Results" work stream, is contributing to the Good Lay Summary Practice initiative and was co-author on PFMD Plain Language Summary guidance for scientific articles. Thereafter, he assumed the role of Director Global Regulatory Affairs in BioNTech serving as CTIS (Clinical Trial Information System) Lead supporting all aspects of clinical trial authorizations in EU and EEA. He has lately started his own consultancy "RSW – RegulatoryScienceWriting" providing support on medical writing and regulatory topics.

Julia A Hild

Julia A Hild is a Senior Medical Writer at Boehringer Ingelheim with a background in pharmaceutical biology and biological sciences. She holds a doctoral degree in human biology and a degree in plain language writing. Since joining Boehringer Ingelheim in 2020, Julia has played a pivotal role in developing lay language documents across multiple therapeutic areas. She specializes in creating patient-friendly materials, including lay summaries, lay protocol synopses, and informed consent forms. Julia also works with visual media, creating scripts and storyboards for videos and comics to support patient understanding. She established processes in close collaboration with the Patient Engagement team to involve patients in the review of lay language documents, ensuring their feedback drives clarity, relevance, and truly patient-centric communication.

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 holds a PhD in molecular and cell biology from the University of Maryland, USA (2013) and completed postdoctoral research in oncology and hematology at the University of Leuven, Belgium. He has authored 16 publications in leading journals including Cancer Discovery, Leukemia, and Nature. From 2018 he held roles in the pharmaceutical industry at BioNTech and Bristol Myers Squibb, where he led scientific publications for Germany across multiple therapeutic areas. Since 2024, he is employed as Associate Director of Global Medical Communications at Regeneron Pharmaceuticals in Munich, Germany, overseeing oncology medical affairs communications for the DACH region. Sergey is a Certified Medical Publication Professional (CMPP™) and an active member of ISMPP. He joined EMWA in 2018 and has served as an EMWA workshop leader since 2020 and an EPDC member since 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; publication guidelines; 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. 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.

Content: This workshop will cover:

- Why we write manuscripts
- The basics: instructions and guidelines
- The sections of a manuscript: what goes where
- How to get started writing
- Submitting the manuscript and dealing with reviewers' comments
- Journal selection
- AI in manuscript writing

Phil Leventhal

Phillip Leventhal, PhD is a Senior Manager, Medical Writing at Thermo Fisher Scientific, where he leads the Publications and Scientific Communications Team. Phil has over 20 years of experience in scientific and medical writing and has written over 200 published peer-reviewed publication and edited hundreds more. As Editor-in-Chief of Medical Writing and Executive Committee member from 2011 to 2020 (now Editor Emeritus) and a long-standing workshop leader for EMWA, he was awarded the Nick Thompson Fellowship in 2021 for exceptional service.

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.

EUROPEAN MEDICAL WRITERS ASSOCIATION

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.

MCF17a Using Writing Guidelines

Profile: As professional medical writers should be reporting guideline champions, this workshop is propaedeutic for any workshops on 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 thoughtful. 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, with the aim of sparing time and improving quality.

Content: Hundreds of guidelines and checklists are available to disclose the results of observational, health outcome, quality of life, mixed-method, and many other types of studies. To complement all of these, Good Publication Practices (GPP) have been developed. Most journals have their own instructions for authors, but almost all of them require authors to follow the publication guidelines. ICH instructions are sometimes vague or unclear, too. 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 work in the era of artificial intelligence.

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, leads EMWA's Salary Survey team, and is a workshop leader and past president of EMWA.

EUROPEAN MEDICAL WRITERS ASSOCIATION

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

Phillip Leventhal, PhD is a Senior Manager, Medical Writing at Thermo Fisher Scientific, where he leads the Publications and Scientific Communications Team. Phil has over 20 years of experience in scientific and medical writing and has written over 200 published peer-reviewed publication and edited hundreds more. As Editor-in-Chief of Medical Writing and Executive Committee member from 2011 to 2020 (now Editor Emeritus) and a long-standing workshop leader for EMWA, he was awarded the Nick Thompson Fellowship in 2021 for exceptional service.

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 Medical Communications Director at Costello Medical, overseeing the company's Medical Communications services, including specialist teams in Publications, Medical Affairs and Creative content across the UK, US and Asia. Her focus is on ensuring that all Medical Communications projects are delivered to the highest possible quality and with exceptional customer service, while maintaining Costello Medical's position at the forefront of industry developments, from the application of digital content and omnichannel approaches through to patient engagement.

Helen has more than twelve years of industry experience, with expertise in strategic publications planning and delivery, as well as client support and account management. She holds the Certified Medical Publication Professional™ (CMPP™) credential from the International Society for Medical Publications Professionals (ISMPP) and is a member of the European Medical Writers Association (EMWA) Professional Development Committee.

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. 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.

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.

MCF30 A Structured Approach to Developing Medical

EUROPEAN MEDICAL WRITERS ASSOCIATION

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

Phillip Leventhal, PhD is a Senior Manager, Medical Writing at Thermo Fisher Scientific, where he leads the Publications and Scientific Communications Team. Phil has over 20 years of experience in scientific and medical writing and has written over 200 published peer-reviewed publication and edited hundreds more. As Editor-in-Chief of Medical Writing and Executive Committee member from 2011 to 2020 (now Editor Emeritus) and a long-standing workshop leader for EMWA, he was awarded the Nick Thompson Fellowship in 2021 for exceptional service.

Stephen Gilliver

Stephen Gilliver is a Manager in Thermo Fisher's Publications and Scientific Communications team. Steve has 16 years' experience in medical writing/medical editing and has written more than 100 published articles. Steve is a former co-editor of the EMWA journal, *Medical Writing*, and a current EMWA workshop leader.

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

Phillip Leventhal, PhD is a Senior Manager, Medical Writing at Thermo Fisher Scientific, where he leads the Publications and Scientific Communications Team. Phil has over 20 years of experience in scientific and medical writing and has written over 200 published peer-reviewed publication and edited hundreds more. As Editor-in-Chief of Medical Writing and Executive Committee member from 2011 to 2020 (now Editor Emeritus) and a long-standing workshop leader for EMWA, he was awarded the Nick Thompson Fellowship in 2021 for exceptional service.

Stephen Gilliver

Stephen Gilliver is a Manager in Thermo Fisher's Publications and Scientific Communications team. Steve has 16 years' experience in medical writing/medical editing and has written more than 100 published articles. Steve is a former co-editor of the EMWA journal, *Medical Writing*, and a current EMWA workshop leader.

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

Sara, PharmD, MSc, is a dedicated medical writer based in Lisbon, Portugal. Starting her freelance career in 2012, she accumulated a decade of experience and became a member of EMWA in 2018. Since 2023, she has also served as a workshop leader within the association. Sara specialises in medical communications and medical education, with a particular focus on medical information. Additionally, she is a co-founder of the Portuguese Medical Writers Association and has been contributing to the pharmaceutical industry since 2021.

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 Medical Communications Director at Costello Medical, overseeing the company's Medical Communications services, including specialist teams in Publications, Medical Affairs and Creative content across the UK, US and Asia. Her focus is on ensuring that all Medical Communications projects are delivered to the highest possible quality and with exceptional customer service, while maintaining Costello Medical's position at the forefront of industry developments, from the application of digital content and omnichannel approaches through to patient engagement.
Helen has more than twelve years of industry experience, with expertise in strategic publications planning and delivery, as well as client support and account management. She holds the Certified Medical Publication Professional™ (CMPP™) credential from the International Society for Medical Publications Professionals (ISMPP) and is a member of the European Medical Writers Association (EMWA) Professional Development Committee.

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. She also delivers guest lectures on the University of Cambridge Therapeutic Sciences MPhil course on Medical Communication.

EUROPEAN MEDICAL WRITERS ASSOCIATION

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 and medical writing 10+ years ago. She is also a passionate educator and activist in medical writing and science communication. She has been a member of EMWA since 2016 and is currently co-chair of the GIMW group, section editor of the journal, and workshop leader.

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.

EUROPEAN MEDICAL WRITERS ASSOCIATION

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

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.

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

MCF8 (a,b) 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 Senior Director of Global Submissions at Veristat. 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 worked as a MW Manager at Trilogy and ICON before joining Certara and now Veristat as one of the Submission Leads. She has a wide range of experience and a particular interest in regulatory documents covering various therapeutic areas.

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.

MDA1 Literature Reviews for Medical Devices

Profile: This workshop is intended for medical writers who are either interested in working with medical devices or who already work with medical devices and are involved in preparing literature reviews for clinical evaluation reports (CERs). Familiarity with European medical device regulations and the CER writing guideline

MEDDEV 2.7/1 rev. 4 is desirable. 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 how to write a literature review as part of a CER. Participants will learn how to prepare a literature review to Medical Device Regulation (MDR) requirements.

Content: The workshop will explain the following:
· the role of the literature review in the clinical evaluation of a medical device;
· the scope of the literature review;
· developing literature search strategies for the subject device and state of the art (current knowledge);
· writing the state of the art section;
· screening and appraising the literature for the subject device;
· data extraction;
· analysing and presenting the literature in the CER;
· literature disposition;
· citing references and listing excluded references.

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).

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;

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).

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.

MDA4 Select the ideal PMCF strategy for a medical device

Profile: This course is intended for advanced medical writers with experience in regulatory writing and PMCF.
We will assume that participants have good knowledge of the Medical Devices Regulation and the requirements for Post-market Clinical Follow-up.

Objective: The requirements for Post-Market Clinical Follow-up (PMCF) as part of Post-Market Surveillance (PMS) under the MDR are well-known and most medical device manufacturers have robust procedures in place. However, selecting the right PMCF activity for a medical device, considering the available clinical evidence, device classification and market history, remains a challenge. User surveys are often associated with low response rates, PMCF studies are sometimes conducted with inappropriate endpoints, and registries might provide incomplete information. Therefore, it is crucial to identify the most suitable PMCF method right away to save time and costs.
The workshop will briefly review the PMCF requirements under the EU MDR 2017/745 and will then dive into different methods to collect clinical data in the post-market phase. This includes user surveys, different designs for PMCF studies, registries, or electronic health records. Participants will have the chance to work on several case studies to learn how to select the ideal PMCF activity for medical devices with different requirements regarding the expected clinical evidence.

Content: Short introduction to Annex XIV Part B of EU MDR 2017/745 (Post-Market Clinical Follow-up)
User surveys:
Best practice tips to plan and set up a user survey
Case study
PMCF investigation:
Common pitfalls with PMCF investigation plans
Case study
Additional PMCF activities: device registries, electronic health records, social media listening
Practice with a fictional medical device

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.

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 (PhD in Biology) has been a regulatory MW for >20 years, covering both pharmaceuticals and medical devices. Her core competencies include clinical trials and submissions documents, data disclosure and protection, and project and people management. Over the years, she took on a wide range of industry positions, as freelancer, as employed regulatory writer, and as head of medical writing departments in the CRO and big pharma settings. She currently leads the MW pediatrics Immunology portfolio at Johnson & Johnson Innovative Medicine. Raquel is an active EMWA member since 2006, serving in various roles, is currently Editor-

in-Chief of Medical Writing and member of the EMWA Executive Committee.

MDF3 Writing Clinical Investigation Plans for Medical Devices

Profile: his foundation-level workshop is designed for professionals who:

- Have never written a Clinical Investigation Plan (CIP), also referred to as a clinical study protocol, for a medical device.
- Are transitioning from the pharmaceutical industry to medical devices.
- Have some experience writing CIPs and would like to deepen their understanding of the document, its regulatory context, and strategic considerations.

Objective: By the end of this workshop, participants will be able to:

- Understand the purpose, structure, and regulatory requirements of a Clinical Investigation Plan for medical devices.
- Develop a CIP that meets European regulatory expectations.
- Apply best practices when drafting each section of the document.
- Recognize the strategic importance of key sections and understand how they influence the conduct and success of a clinical investigation.
- Locate and use relevant information efficiently during the writing process.

Participants with prior experience will gain a more comprehensive understanding of the rationale behind CIP requirements and the considerations that support high-quality protocol development.

Content: This workshop focuses on Clinical Investigation Plans for medical devices within the European regulatory framework.
Using a practical, chapter-by-chapter approach, participants will learn how to develop a complete CIP from start to finish. Each section of the document will be explained in detail, including its purpose, required content, and common pitfalls.
Beyond regulatory requirements, the workshop explores the strategic implications of protocol design decisions and their impact on study execution.
The workshop also provides practical guidance, writing tips, and techniques for identifying and gathering the information needed to prepare a robust and compliant Clinical Investigation Plan.

Beatrix Doerr

After completing her degree in veterinary medicine and earning a doctorate in parasitology, Beatrix Doerr began her career as a veterinary surgeon before moving

into clinical research. Over the course of her industry career, she held positions of increasing responsibility, culminating in her role as Head of the European Transcatheter Heart Valve Program. In this position, she led five departments, including Pre- and Post-Market Clinical Studies, Department Coordination, Implant Specialists, and Safety.
Since 2011, Beatrix has been the founder and managing consultant of Coriuvar, an independent consultancy specializing in cardiovascular medical devices. Her work focuses primarily on regulatory medical writing, scientific publications, and safety reporting, supporting clients throughout the clinical and regulatory lifecycle of medical devices.

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 Writing Effective Instructions for Use (IFUs) for

EUROPEAN MEDICAL WRITERS ASSOCIATION

Medical Devices

Profile: This workshop is designed for medical writers who are new to medical device regulatory writing or who would like to strengthen their understanding of Instructions for Use (IFUs) under the EU Medical Devices Regulation (MDR 2017/745), including relevant MDCG guidance and current regulatory expectations. It is also suitable for writers transitioning from pharmaceutical to medical device documentation.

Objective: By the end of this workshop, participants will be able to:

- Understand the regulatory requirements governing IFUs under EU MDR 2017/745
- Identify the key sections and mandatory content of an IFU
- Recognize how information is sourced from clinical, technical, usability, and risk management documentation
- Apply principles of clear, user-centered writing to improve readability and usability
- Contribute effectively to the planning, drafting, review, and maintenance of IFUs
- Recognize common pitfalls and implement best practices to improve document quality

Content

1. Regulatory Framework
- Purpose and regulatory role of IFUs
- Key EU MDR requirements and definitions
- Electronic IFUs and current considerations

2. Anatomy of an IFU
- Required content and document structure
- Indications, contraindications, warnings, precautions, and residual risks
- Consistency with device labeling and supporting documentation

3. Information Sources
- Legacy devices versus new devices
- Using information from clinical evaluations, clinical investigations, risk management files, usability engineering documentation, and technical documentation
- Managing cross-functional inputs and stakeholder reviews

4. Best Practices for Drafting
- Writing clearly for the intended user
- Communicating risks effectively
- Improving readability, consistency, and document quality
- Managing revisions and review cycles

5. Usability and User-Centered Communication
- Applying usability principles to IFU development
- Images, graphics, symbols, and visual communication
- Supporting safe and effective device use

6. Beyond the IFU

- How IFU content is reused across regulatory and product documentation
- Maintaining consistency across clinical, regulatory, and marketing materials

Workshop Format

The session combines presentations, practical examples, and interactive discussions. Participants will review real-life IFU excerpts, identify common deficiencies, and explore approaches to creating compliant, user-friendly documentation that adds value for both manufacturers and end users.

Key Takeaway

Gain the knowledge and confidence to support the development of high-quality Instructions for Use that meet regulatory expectations, enhance user understanding, and contribute to the safe and effective use of medical devices.

Laura C. Collada Ali

Currently working as a Senior Medical Writing Manager at Trilogy Writing & Consulting, she has over 25 years of experience in writing, editing, and managing medical and scientific documentation for diverse clients and audiences. Laura is EMWA-certified and holds multiple certificates in linguistics, pharmacology, medical devices, and clinical research. She has served EMWA in different roles: Professional Education Committee member and chair, as well as a member of the Executive Committee.

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 introductory workshop is designed for professionals who wish to begin working in safety reporting and safety writing for medical devices, as well as those who would like to gain a broader understanding of this rapidly evolving field.

It is particularly suitable for medical writers, clinical research professionals, regulatory affairs specialists, and others seeking to understand the processes, regulations, and terminology used in medical device safety. Participants will learn key concepts, including the distinction between adverse events, serious adverse events, device deficiencies, and other safety-related definitions.

No previous experience in safety reporting is required.

Objective: By the end of this workshop, participants will be able to:

- Understand the role of safety reporting throughout the lifecycle of a medical

device.
- Become familiar with the European and international regulatory framework governing medical device safety.
- Apply key safety terminology and reporting concepts correctly.
- Recognize the types of safety documentation prepared by medical writers and the purpose of each.
- Appreciate how safety data influence clinical investigations, regulatory submissions, and post-market activities.

As safety reporting has become an increasingly important area within the medical device industry, this workshop provides an excellent foundation for medical writers wishing to expand their expertise into this growing specialty. The knowledge gained will also enhance participants' understanding of safety considerations when preparing other clinical and regulatory documents, such as Clinical Investigation Plans (CIPs).

Content: The workshop consists of two complementary parts that provide a comprehensive introduction to safety reporting and safety writing for medical devices.
Part 1 introduces the fundamentals of medical device safety reporting, including:
- The role of medical writers in safety reporting
- Key definitions and terminology
- Applicable regulations and guidance documents
- IMDRF coding principles
- Safety reporting requirements
- The Clinical Investigation Summary Report Form
- Individual case safety reports and summary safety reports

Part 2 expands on these concepts and explores additional safety-related documentation and processes, including:
- Literature reviews for signal detection and trending
- Patient narratives
- Safety management plans and coding
- Clinical Events Committee (CEC) and Data Safety Monitoring Board (DSMB) charters and guidelines
- Risk management documentation
- Post-Market Surveillance (PMS) Plans
- Periodic Safety Update Reports (PSURs)
- Summary of Safety and Clinical Performance (SSCP)
- Safety sections of informed consent forms, Clinical Investigation Plans (CIPs), and Instructions for Use (IFUs)

Throughout the workshop, practical examples and real-world scenarios are used to illustrate how safety information is collected, evaluated, documented, and communicated across the clinical and regulatory lifecycle of medical devices.

Beatrix Doerr

After completing her degree in veterinary medicine and earning a doctorate in parasitology, Beatrix Doerr began her career as a veterinary surgeon before moving into clinical research. Over the course of her industry career, she held positions of

increasing responsibility, culminating in her role as Head of the European Transcatheter Heart Valve Program. In this position, she led five departments, including Pre- and Post-Market Clinical Studies, Department Coordination, Implant Specialists, and Safety.
Since 2011, Beatrix has been the founder and managing consultant of Coriuvar, an independent consultancy specializing in cardiovascular medical devices. Her work focuses primarily on regulatory medical writing, scientific publications, and safety reporting, supporting clients throughout the clinical and regulatory lifecycle of medical devices.

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 elopment 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

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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 Lead Clinical Evaluation Specialist at Stryker with more than 7 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

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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

Currently working as a Senior Medical Writing Manager at Trilogy Writing & Consulting, she has over 25 years of experience in writing, editing, and managing medical and scientific documentation for diverse clients and audiences. Laura is EMWA-certified and holds multiple certificates in linguistics, pharmacology, medical devices, and clinical research. She has served EMWA in different roles: Professional Education Committee member and chair, as well as a member of the Executive Committee.

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.

MDF10 Introduction to Combination Products in the US and EU

Profile: This workshop is aimed at medical writers working in the regulatory field. Basic knowledge of regulations governing medicinal products and medical devices will be useful. Having completed the workshop Going from Pharma to Medical Devices would be helpful but is not a prerequisite.

Content: Combination products are regulated differently depending on their "Primary Mode of Action (PMOA)," their product configuration, and the regulatory body. Understanding how a combination product is regulated will be essential in understanding the documentation required in the regulatory submission. In the US, the submission process is different compared to that in the EU – however, much of the content is already an existing part of the technical documentation of the device and drug component, regardless of jurisdiction.
This workshop will provide an introduction to combination products and the different types. We will cover the parts of a US submission and an EU submission, depending on the combination product PMOA, that are relevant to medical writing.
A few case-studies will be presented and discussed.

Objective: The objective of this course is to provide an introduction to the regulations governing combination products (with focus on drug-device combinations [DDCs]) as they are defined in the US and EU, respectively. Additionally, we will touch on the documentation required for these types of submissions and the role of medical writers in developing these documents.

Cherry Malonzo

Cherry Malonzo Marty is an MD and Biomedical Engineer by training. She has over 10 years of experience working in various functions in education, clinical settings, research, and regulatory affairs. She has co-authored the book chapter "Combination Products Evolving Global Regulatory Environment" in the 1st edition of The Combination Products Handbook published in 2023. Since 2019, she has been working as a freelance regulatory writer and consultant for medical device and combination product submissions in the US and EU. Since 2021, she is the module leader for International Regulatory Affairs at the sitem Center for Translational Medicine and Biomedical Entrepreneurship in Bern, Switzerland. Apart from her freelancing projects, she currently works part-time as the

Regulatory and Quality writer for a spin-off of ETH, Zürich

MDF11 Introduction to Medical Devices

Profile: This workshop is for new/aspiring medical writers who are interested in writing for medical devices, or experienced medical writers, who usually work in medical communications or in regulatory (drug development) and want to learn about medical devices. This is an introductory workshop, so the only ones who will not benefit from it are those who already work in medical devices and have an understanding of the processes and documents involved.

Objective: To give attendees an overview of what is a medical device, the classification rules, regulatory landscape (focusing primarily in the European Union), and the main documents that medical writers are involved with. The workshop will also explore the role of the medical writer, the necessary skills and possible challenges to overcome when working in the medical devices area.

Diana Ribeiro

Diana Ribeiro, MPharm, is a pharmacist by training. Having worked for 10+ years in hospital and community pharmacies, she then transitioned to medical writing in late 2019. Working across a number of therapeutic areas, she has written many different types of documents, both in medical communications and the regulatory field. In 2020, she started working in medical devices, authoring clinical evaluation reports under the medical devices directive and the medical devices regulation (MDR), as well as other documents in this area.

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.

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 holds a PhD in molecular and cell biology from the University of Maryland, USA (2013) and completed postdoctoral research in oncology and hematology at the University of Leuven, Belgium. He has authored 16 publications in leading journals including Cancer Discovery, Leukemia, and Nature. From 2018 he held roles in the pharmaceutical industry at BioNTech and Bristol Myers Squibb, where he led scientific publications for Germany across multiple therapeutic areas. Since 2024, he is employed as Associate Director of Global Medical Communications at Regeneron Pharmaceuticals in Munich, Germany, overseeing oncology medical affairs communications for the DACH region. Sergey is a Certified Medical Publication Professional (CMPP™) and an active member of ISMPP. He joined EMWA in 2018 and has served as an EMWA workshop leader since 2020 and an EPDC member since 2023.

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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 holds a PhD in molecular and cell biology from the University of Maryland, USA (2013) and completed postdoctoral research in oncology and hematology at the University of Leuven, Belgium. He has authored 16 publications in leading journals including Cancer Discovery, Leukemia, and Nature. From 2018 he held roles in the pharmaceutical industry at BioNTech and Bristol Myers Squibb, where he led scientific publications for Germany across multiple therapeutic areas. Since 2024, he is employed as Associate Director of Global Medical Communications at Regeneron Pharmaceuticals in Munich, Germany, overseeing oncology medical affairs communications for the DACH region. Sergey is a Certified Medical Publication Professional (CMPP™) and an active member of ISMPP. He joined EMWA in 2018 and has served as an EMWA workshop leader since 2020 and an EPDC member since 2023.

MSF15 General Nutrition for Medical Writers

Profile:

- Medical writers with entry-level nutrition knowledge.
- Medical writers seeking to diversify their expertise into nutrition-related topics.
- No prior experience in nutrition science or writing is required.

Objective: This workshop corresponds to medical writers' needs by addressing challenges such as:

1. Writing about nutrition studies, which are increasingly incorporated into medical research.
2. Preparing regulatory documents and studying protocols involving nutritional interventions.
3. Communicating public health messages to address chronic disease risk factors linked to diet.
4. Developing patient-facing content, such as informed consent documents and dietary guidance.

Participants will acquire skills to:

1. Critically analyze nutrition studies and synthesize findings into engaging, accessible materials.
2. Write confidently about nutrition in regulatory, academic, and public contexts.
3. Tailor content for healthcare professionals, researchers, and patients.

Content: Nutrition is a cornerstone of health and disease prevention, making it an important topic for medical writers. This workshop provides foundational knowledge in nutrition science, equipping participants with the skills needed to interpret and communicate dietary research effectively.

Through interactive sessions, participants will gain knowledge on key nutrition concepts, including macronutrients/micronutrients, energy balance, dietary patterns, evidence-based guidelines, clinical nutrition applications, public health aspects, and emerging nutrition research. This workshop emphasizes practical application, offering tools to critically evaluate nutrition studies and adapt findings for diverse audiences.

By the end of the workshop, attendees will be able to confidently write about nutrition topics, from patient information leaflets to peer-reviewed manuscripts. Whether you're new to medical writing or looking to expand your expertise, this workshop will help you navigate the intersection of nutrition science and effective communication.

Maria Carolina Rojido

Carolina is a general physician with a master's in health administration, and certificates in lifestyle medicine, plant-based nutrition, and nutrition coaching. She worked in the United States for nine years, managing and writing documents and medcomms for oncology, imaging and clinical gerontology research. Now based in France, she works as a freelance medical writer and sustainable nutrition coach, interacting with lay and scientific audiences. She collaborates with the True Health Initiative, the Mediterranean Editors and Translator Meetings, and the European Lifestyle Medicine Organisation and has also worked with the Center for Nutrition Studies at Cornell University, the Physicians Association for Nutrition.

MSF16 Psychology essentials for medical writers

Profile: This workshop is aimed at medical writers with little or no experience of writing documents in psychological sciences and who would like to learn more about the study of human behaviours, attitudes, perceptions and emotions. As a foundation workshop, no prerequisites are required.

Objective: The workshop will introduce key psychological concepts and will outline the main research methods and procedures used to observe, describe, predict, and explain behaviours and mental processes.
The aim is to educate participants on conventions of writing in psychology.

Content: The content will cover the purpose and types of psychology documents, sources used in writing psychology, differences between qualitative and quantitative studies, the use of the American Psychological Association (APA) format, psychology terms, ethics, main tests and measurement used to perform research objectives in various fields. There will be particular emphasis on practical aspects throughout questions and exercises.

Alessia Spina

Alessia is a clinical and health psychologist, a research assistant and a medical writer with 10+ years of research experience at IRCCS Policlinico San Donato, a research hospital specialized in cardiovascular treatments.
Her work focuses on psycho-cardiology, exploring the impact of art therapy and environmental psychology interventions in patients with rare and congenital heart diseases. She manages interdisciplinary research projects integrating clinical practice

and creative methodologies with a prominent aptitude for medical communications, research manuscripts and grant writing.
She holds degrees in Interpreting and Translation, Psychological Sciences and Techniques, and Clinical Psychology, with expertise in art therapy, sport psychology, therapeutic photography and expressive writing.

MSF17 Oncology essentials for medical writers

Profile: This workshop is designed for medical writers with limited or no experience in oncology. Participants should have a general understanding of clinical study designs, ICH-GCP guidelines, and basic clinical trial statistics.

Objective: To equip medical writers with essential skills for oncology studies, the workshop aims to cover the principles of oncology diagnosis and therapy, relevant drug development guidelines, and their application in document drafting. Given the complexity of oncology trials, which involve intricate designs, diverse drug actions, varied patient populations, and specific objectives and endpoints, understanding these aspects is crucial.

Ekaterina Weith

Ekaterina, a trained biologist, began her journey in Oncology drug development in 2005. Ekaterina brings experience in Medical Writing, Medical Data Review and Clinical Sciences. Her career includes leadership roles in biotech companies and contract research organizations, where she developed internal Oncology training programs. Ekaterina holds a Master's degree in Pharmaceutical Medicine and is currently pursuing her PhD. At Immatics, she is part of Clinical Sciences team focusing on innovative TCR-based anticancer therapies.

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.

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.

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).

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.

John Carpenter

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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 and consultant for Trilogy Writing & Consulting as Medical Writing Manager. In 2015 Thomas moved to the headquarters of Merck Healthcare KGaA in in Germany and is responsible for all regulatory medical writing documents from Phase I to post-marketing studies across all therapeutic areas.

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 Kovacevic has worked in medical writing and regulatory affairs within the CRO and pharmaceutical industry since 2006 and has been an active member of the European Medical Writers Association (EMWA) since 2009. She has over 18 years of experience in medical writing leadership, specialising in regulatory writing, strategic consultancy, operational management, training, and the development of high-

performing global medical writing teams.
Jules is a founding partner and Head of Strategy and Operations at Ambermed Medical Writing & Consultancy, where she provides strategic regulatory writing and consultancy services to pharmaceutical, biotechnology, and medical device companies.
Throughout her career, Jules has successfully established and led global medical writing teams, developed mentoring programmes, and created career development pathways for medical writers at all stages of their careers. She is passionate about developing people and fostering collaborative, supportive working environments that promote professional growth, quality, and staff retention.
Within EMWA, Jules has held several positions. She served as Co-Education Officer from May 2022 until June 2025. She stood in as Interim Conference Director in June 2025 and was elected Conference Director in May 2026. She also serves as Co-Chair of the Regulatory Writing Special Interest Group (now incorporating Pharmacovigilance Writing).

PTA16 Oral Presentations: Skills to Help You Survive or Even Shine

Profile: This workshop is suitable for anyone who wants to reflect on or improve their oral presentation skills. 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 an integral and valuable part of the workshop is an opportunity to deliver a short presentation in English, and receive constructive feedback – but see below. (We do not cover slide design and construction of a story, which is addressed in the workshop Developing Effective Oral Presentations, MCF22.)

Objective:
- 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 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

- For accreditation, a participant is asked to prepare a short presentation (3 minutes) with up to 10 slides, prepared during the pre-workshop assignment. Delivering a presentation is not obligatory (unless accreditation is desired). However, an integral part of the workshop is the opportunity to deliver a presentation, receive feedback and provide feedback on other participants' presentations – and past participants have found this a valuable experience.
- The workshop is limited to 10 participants, allowing comfortable time for all presentations and feedback.
- For those who find presenting a scary experience – that's a reason to come along! So, don't be worried – 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 Finance 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.

EUROPEAN MEDICAL WRITERS ASSOCIATION

Carola Krause

Carola Krause is an Associated Principal Medical Writer at Trilogy Writing & Consulting, focusing on non-clinical and clinical regulatory writing. Based in Potsdam, Germany, she has a postdoctoral background in molecular stem cell biology and extensive hands-on experience in academic and pharmaceutical research, project management, and all stages of drug development.

As a long-term EMWA member, Carola has contributed to its educational program, founded and chaired the Creative Team and the Sustainability Special Interest Group, and served as EMWA's President (2020–2022). She continues to represent EMWA as an ambassador and AI liaison for the Visual Communications Special Interest Group.

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.

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

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PTA20 Insights into the journey to leadership in medical writing

Profile: This workshop is intended for medical writers who are considering a transition into people management, are new to a line management role, or are navigating how to balance managing others while remaining actively involved in writing projects. It is suitable for writers in regulatory, scientific, or related medical writing roles who want a clearer understanding of what people management entails before pursuing it, or who are in the early stages of leading others. No previous management training is required. Prior experience as a medical writer is expected.

Objective: As medical writers advance in their careers, many step into people management roles without formal preparation for the relational and leadership challenges involved. This workshop aims to address this gap by focusing on the transition from individual contributor to manager, with particular emphasis on balancing new responsibilities and relationships. Participants will learn to identify common challenges during the transition to management, be exposed to practical strategies for managing people, and explore career growth paths and support systems to help make the leap into a leadership role.

Content: This workshop combines short slide presentations, facilitated discussions, and scenario-based exercises grounded in management challenges. Topics include assessing readiness for management, shifting mindset from "doer" to enabler, managing former peers, delegation, prioritization, expectation and feedback management, and navigating difficult conversations. Participants will also reflect on career progression and organizational support mechanisms. Practical tools and takeaways will aim to help participants apply learning immediately to their own roles or career plans.

Kleopatra Kouroupaki

Dr. Kleopatra Kouroupaki holds a PhD in Neurophysiology and a BSc in Physics and has nine years of experience as a regulatory medical writer. She has spent over two years as line manager, where she leads a team of medical writers while also remaining actively involved in high-stakes regulatory writing projects. Her current role requires balancing people management, mentoring, and strategic decision-making with hands-on writing contribution. She has recent, firsthand experience navigating peer-to-manager dynamics, managing competing priorities, and aligning team development with organizational goals that she wishes to share. Drawing on this experience, she will share practical, real-world insights to help others explore whether management is the right path for them and, if so, how to approach the transition with clarity, confidence, and balance. In the past, she has presented educational talks and a webinar at AMWA and a workshop on consistency in writing dossiers for 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.

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.

PTF21 Health-related Quality of Life

Profile: This workshop is aimed at medical writers who deal with health-related quality of life instruments (HRQoL) or patient-reported outcome measures (PROMs) 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 gain an understanding of how to appraise HRQoL measures and report their use in studies. We will also explore various approaches for generating the HRQoL data that are used in cost-utility analysis.

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 associate 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. Here, she has worked at WHO Regional Office, Odense University Hospital, 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.

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 Executive Director, Head of Global Medical Writing, 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.

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 Medical Communications Director at Costello Medical, overseeing the company's Medical Communications services, including specialist teams in Publications, Medical Affairs and Creative content across the UK, US and Asia. Her focus is on ensuring that all Medical Communications projects are delivered to the highest possible quality and with exceptional customer service, while maintaining Costello Medical's position at the forefront of industry developments, from the application of digital content and omnichannel approaches through to patient engagement.

Helen has more than twelve years of industry experience, with expertise in strategic publications planning and delivery, as well as client support and account management. She holds the Certified Medical Publication Professional™ (CMPP™) credential from the International Society for Medical Publications Professionals (ISMPP) and is a member of the European Medical Writers Association (EMWA) Professional Development Committee.

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. She also delivers guest lectures on the University of Cambridge Therapeutic Sciences MPhil course on Medical Communication.

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 worketf40d 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. The increasing need to safeguard the accuracy of AI-generated CSR content will also be considered together with discussion around appropriate quality review mechanisms. Although the workshop is applicable to other types of medical writing it will primarily use clinical study reports as working examples.

EUROPEAN MEDICAL WRITERS ASSOCIATION

Alison McIntosh

Alison has provided medical writing education, training and consultancy services to the pharmaceutical industry for almost 30 years, During this time she 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 a wealth of experience developing and leading medical writing workshops and in-house training courses for pharmaceutical companies covering different aspects of medical writing. She has been an EMWA workshop leader since 2001, and currently 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 visualisation 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.

Ana Goios

Based in Portugal, Ana Goios works remotely as the head of medical writing for P95/Julius Clinical. She leads a remote team of 18 medical writers working on clinical trial and real-world evidence documents, supporting with resource planning, process improvement, and business development initiatives. As a medical writer, she prepares reports, manuscripts, posters, and slide decks, often with a strong visualisation component. 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 visualisation and design. Her multidisciplinary background allows her to produce complete medical

communication documents using data analysis tools and producing graphics, illustrations, and texts.
Ana has been an EMWA member since 2018 and has since then attended EMWA Professional Development Program Workshops and obtained the EPDP Foundation Certificate. She has been a workshop leader since 2021.

PTF43 Optimizing writing efficiency by taking advantage of Microsoft Word's hidden options

Profile: Participation profile: This workshop is intended for medical writers with basic to intermediate skills in Microsoft Word who want to become more efficient at using Microsoft Word in their jobs. There are no prerequisites for this workshop.

Objective: In this hands-on workshop, writers will learn and apply lesser-known tips and tricks in Microsoft Word, with the aim of improving their writing efficiency and reducing the burden associated with conventional use of Word.
Attendees will learn how to organize their most-used commands for easy access, to apply keyboard shortcuts that are useful for their writing needs, to more efficiently create and revise tables, and to create standardized styles. Each topic will be introduced in a short lecture with class participation, followed by a hands-on exercise and group discussion.

Jacqueline Janowich Wasserot

Dr. Janowich Wasserott is a Senior Medical Writer on the Publications and Scientific Communications team of the PPD clinical research business of Thermo Fisher Scientific. She is the leader of the 'Tech Tips' focus group, where she provides departmental trainings on practical tips to improve writing efficiency using Microsoft Word, Excel, and PowerPoint. Before becoming a medical writer, Dr. Janowich Wasserott studied how the brain handles the demands of task switching and task planning. She has a keen interest in improving processes and enjoys finding new ways to elevate the quality and efficiency of writing deliverables.

PTF45 Working with key Opinion Leaders (KOLs) in Medicine

Profile: This standalone workshop is designed for all medical writers who have dealings with Key Opinion Leaders (KOLs) as part of their job. KOLs are an integral element of medical publications and presentations yet there is little information on who they are and how they should be managed. This workshop examines the different types of KOLs in medicine, the considerations behind using KOLs as well as strategies to interact with them. As an interactive workshop, participants are requested to share their own experiences with KOLs (if any) during the workshop. Please also bring your computer to the workshop.

Objective: By the end of this workshop participants will be aware of the main types of KOLs in medicine, the advantages and disadvantages of working with them, as well as learning relevant strategies to interact with KOLs.

EUROPEAN MEDICAL WRITERS ASSOCIATION

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, his most recent role was as the Key Expert Manager for a dental intraoral scanner company. Diarmuid is also a general freelance writer and is currently completing a PhD in Public Health with a focus on Patient-Reported Outcome Measures (PROMs) in Low to Middle Income Countries.

PTF46 Critical Thinking how to assess data and info with an unbiased eye

Profile: This workshop will introduce key principles of critical thinking that underpin clear, accurate, and responsible scientific communication. It is aimed at medical writers who need to interpret and communicate data objectively, with accuracy and with nuance. No prior training in data analysis is required. Participants wanting to strengthen their ability to assess scientific claims – particularly within clinical research – will find this session a valuable foundation.

Objective: Critical thinking is essential for all communicators. As medical writers, we are routinely required to interpret complex research, evaluate the robustness of evidence, and present balanced, narratives to regulators, healthcare professionals, and patients. Yet clinical data may be unintentionally or deliberately misrepresented: graphical choices, selective reporting, and emphasis on relative rather than absolute effects can all distort how results appear.

This workshop aims to help participants identify common pitfalls in reasoning and assess the strength of evidence. A particular focus will be placed on critically thinking about clinical data. Participants should leave equipped to evaluate scientific arguments more confidently, avoid common analytical traps, and communicate clinical data in a transparent and scientifically rigorous way.

Content: Participants will be guided through common areas of 'bad science' and the significant consequences of misleading or inaccurate science communication. A dedicated section will focus on the critical evaluation of clinical data, which will address key areas such as exposure presentation, risk interpretation, statistical significance, and the appropriate use and limitations of subgroup analyses.

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.

Savanna LeBoff

Savanna Leboff holds a degree in Natural Sciences with a specialisation in pharmacology from the University of Cambridge. After graduating in 2021, she joined Trilogy Writing & Consulting and is now a senior medical writer. Savanna has contributed to a wide range of regulatory documents across diverse therapeutic areas and has a strong interest in plain language writing. Through her work, she has developed a particular focus on applying critical thinking to the interpretation and communication of scientific data.

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

Phillip Leventhal, PhD is a Senior Manager, Medical Writing at Thermo Fisher Scientific, where he leads the Publications and Scientific Communications Team. Phil has over 20 years of experience in scientific and medical writing and has written over 200 published peer-reviewed publication and edited hundreds more. As Editor-in-Chief of Medical Writing and Executive Committee member from 2011 to 2020 (now Editor Emeritus) and a long-standing workshop leader for EMWA, he was awarded the Nick Thompson Fellowship in 2021 for exceptional service.

Stephen Gilliver

Stephen Gilliver is a Manager in Thermo Fisher's Publications and Scientific Communications team. Steve has 16 years' experience in medical writing/medical editing and has written more than 100 published articles. Steve is a former co-editor of the EMWA journal, Medical Writing, and a current EMWA workshop leader.

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.

Laura C. Collada Ali

Currently working as a Senior Medical Writing Manager at Trilogy Writing & Consulting, she has over 25 years of experience in writing, editing, and managing medical and scientific documentation for diverse clients and audiences. Laura is EMWA-certified and holds multiple certificates in linguistics, pharmacology, medical devices, and clinical research. She has served EMWA in different roles: Professional Education Committee member and chair, as well as a member of the Executive Committee.