42nd EMWA Conference

4th EMWA Symposium

Thursday 12 May 2016

EUROPEAN MEDICAL WRITERS ASSOCIATION

10–14 May 2016

Sheraton Munich Arabellapark Hotel
Munich, Germany

www.emwa.org

EUROPEAN MEDICAL WRITERS ASSOCIATION

Contents

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Remember to download the EMWA conference app

Available on the App Store

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Message from the President and Conference Director

Dear Delegates

Registration for the EMWA Munich Spring Conference is now open and your Executive Committee and an army of volunteers have been working hard to put together another stimulating programme.

Our spring conference content has flourished from a sound offering of workshops with a Symposium in May 2014 into the multi-layered programme that we now offer.

35 foundation and 16 advanced workshops, the Freelance Business Forum and the buzz of medical writers networking will underpin the conference. The 4th Symposium Day on 'Scientific and Medical Communication Today' will bring us together with cross-industry speakers, panellists and regulators for lively debate on our ever-changing professional landscape. Experienced members will enjoy the 2nd Expert Seminar Series, covering topics as diverse as clinical trial disclosure; referencing software; running medical writing groups in India, China and Japan; artificial intelligence; and adaptive study design.

Special Interest Groups (SIGs) will provide EMWA's very own 'talking shops' on hot topics that are expected to develop and endure. The Pharmacovigilance Special Interest Group (PV SIG) will delve into issues that impact the PV documents that we write, and with the direct involvement of regulators you can ask the questions that matter to you. As EMWA and AMWA (American Medical Writers Association) publish the open-access resource CORE (Clarity and Openness in Reporting: E3-based) Reference in May 2016, we will launch the Regulatory Public Disclosure SIG (RPD SIG), a natural follow-up to CORE Reference. RPD SIG will focus on public disclosure of clinical regulatory documents, with the expectation of an impact on their content and structure, and increase in their range, and public disclosure creating the need for new documents that the medical writer will support. The SIGs allow EMWA and its members to contribute to important conversations around topics that we know will impact on our industry in the coming years.

We will also be holding an internship forum, where potential internees new to medical writing and companies seeking interns can network.

With something for everyone – from entry-level right through to experienced members – we invite you to join us in lively Munich from 10 to 14 May 2016 for another memorable conference.

Sam Hamilton
President

Slávka Baróniková
Conference Director

EUROPEAN MEDICAL WRITERS ASSOCIATION

Quick guide to EMWA conference sessions

To guide you through the training and education options available to you at EMWA conferences, we have created an at-a-glance overview to help you plan your conference participation.

Full details of workshops, seminars and the EMWA Symposium can be found in this brochure and the online conference planner.

FOUNDATION WORKSHOPS

Foundation level workshops are aimed at those who are new to a topic, or who have up to a moderate level of experience in it. They have a maximum group size of 32 and last 3 or 3.5 hours. Foundation level workshops are part of the EMWA Professional Development Programme (EPDP). They can be done to gain credits towards an EPDP foundation certificate.

ADVANCED WORKSHOPS

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. Advanced level workshops are part of the EPDP and can be done to gain credits towards an EPDP advanced certificate.

SEMINARS

Free seminars are included in the EMWA conference programme to complement the EPDP programme and give new and experienced medical writers an opportunity to network, learn and share knowledge with their colleagues.

EXPERT SEMINAR SERIES

The Expert Seminar Series (ESS) is for experienced medical writers, heads of medical writing departments, and industry leaders from other disciplines. The topics in this series are for those who want to learn about the latest developments affecting the world of medical writing and play a role in shaping its future.

ESS sessions include 2 seminars, and each session must be booked as a whole. Individual seminars cannot be booked.

THE EMWA SYMPOSIUM

The EMWA Symposium is a 1-day event organised during the spring conference. The theme for each symposium focuses on a specific industry concern and explores the fast changing landscape of medical and scientific communication and writing. Invited speakers and experts cover the symposium topic from a 360-degree perspective, and discuss it with panellists and symposium attendees during panel discussions. Our symposiums are an opportunity for inexperienced writers to learn about the chosen topic, and for the more advanced writers, they offer a unique chance to exchange ideas with presenters, panellists and EMWA colleagues.

EMWA Professional Development Programme

The EMWA Professional Development Programme (EPDP) provides high-quality training for medical writers through workshops and homework assignments. All workshops are taught by leaders with hands-on expertise in the topic and are approved by the EMWA Professional Development Committee.

EMWA workshops usually have both a pre-workshop assignment or pre-reading, and all have an assessed post-workshop assignment. You can gain credits, which allow you to obtain an EPDP certificate. The element of assessment ensures that EMWA credits represent a real attainment, and are a valuable addition to your curriculum vitae. Credits are added to your personal professional development record, which you can access through the EMWA website. See below for more information about how to gain credits and obtain an EPDP certificate.

Delegates not interested in gaining credit may attend workshops without doing the assignments, and receive a certificate of attendance.

Advanced workshops: there are no formal prerequisites for attending advanced workshops. However, there will not be time during advanced workshops to cover the basics of the subject for attendees who do not fit the profile in the workshop description.

Gaining EPDP credits

To receive credit for a workshop, you must:

- After registering for the conference, **download your pre-workshop assignment from the EMWA website,** complete the pre-workshop assignment (usually 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 or pre-reading that you need to download.
- Attend the workshop.
- Complete the post-workshop assignment (up to 3 hours) to a satisfactory standard, and submit it by the deadline given. The workshop leader will supply you with the post-workshop assignment.

The times required to complete the assignments are a general guide only.

Late registrants: 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 cannot be accepted after the workshop.

Please note: it is no longer necessary to enrol for the EPDP. Instead, an administration fee will be charged for issuing certificates. Members who have previously paid the EPDP enrolment fee will be exempt from this for the 5 years from their date of enrolment.

For full information about the EPDP and how credits are awarded, see the EPDP Brochure.

EMWA certificates

The EPDP is divided into 6 subject areas: Drug Development, Language and Writing, Medical Communication, Medical Science, Professional Techniques, and Soft Skills.

There are 2 levels of certificate: foundation and advanced.

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

- At least 5 foundation workshops in a single subject area to qualify for a specialised certificate in that option.
- Foundation workshops in at least 2 subject areas, but no more than 4 workshops per area, for a multidisciplinary certificate.

An EMWA advanced certificate is awarded for credits in any 8 advanced workshops. Members do not need to have a foundation certificate in order to register for advanced workshops.

Members may obtain more than 1 foundation or advanced certificate after completing the appropriate requirements for each certificate.

General

Workshops are available at EMWA conferences only. Workshops offered will depend on the availability of the workshop leaders. For the full list of EMWA workshops, see the EPDP brochure on the EMWA website.

We welcome ideas for new workshops. If you are interested in developing a workshop, please contact the Education Officer, Barbara Grossman (education@emwa.org).

Fees and registration

Member-only events

Main conference attendance

The main conference attendance is open to EMWA members. Non-members are invited to join EMWA when registering for the conference. Membership costs €130 per year (Europe) or €145 per year (outside Europe).

Conference registration and workshop fees

Conference registration fees are as follows.

	Early registration Deadline: 31 March 2016	Regular registration Deadline: 2 May 2016	Late and on-site registration (3 May onwards)
Full (Tuesday to Saturday)	€620	€750	€1000
2 days	€480	€570	€800
1 day	€320	€370	€450

Registration includes all conference materials, the opening Networking Event and Welcome Reception, Annual Meeting, Freelance Business Forum, Internship forum, all free seminars, easy morning Yoga classes, and lunches and coffee breaks on the days for which you are registered.

Full registration includes attendance at the Symposium. In the case of 2- or 1-day registration, registration must include the day of the Symposium if you wish to attend the Symposium.

Workshop and Expert Seminar Series fees are as follows.

Foundation workshop	Single workshop Double workshop	€160 €320
Advanced workshop	Advanced workshop	€250
Expert Seminar Series (ESS)	1 ESS Session All 3 ESS Sessions	€150 €300

ESS sessions include 2 seminars, and each session must be booked as a whole. Individual seminars cannot be booked

Changes to registration

An administration fee of €25 will be charged for changes to workshop or Expert Seminar Series registration (that is, a change of workshop or expert seminar choice). There is no fee for adding workshops, expert seminars, or social events.

Cancellation of attendance

A refund, less an administration fee of €150, will be made for cancellations of attendance received before 1 April 2016. No refunds will be made after this date, and FULL payment is due.

Accompanying persons

Accompanying persons who would like to attend the opening Networking Event and Welcome Reception and to join the EMWA lunch and coffee breaks must be registered for the conference by the EMWA member they are accompanying. The fee for registered accompanying persons is €333 (full), €152 (2 days) and €76 (1 day). A reduced rate is offered for carers accompanying registered delegates with a disability: €111 (full), €51 (2 days), and €25 (1 day). EMWA reserves the right to ask for proof of disability (e.g. national registration certificate) for delegates claiming the reduced rate for their accompanying person.

Events open to non-members

ESS + Symposium Package

This package, aimed at experienced medical writers, includes attendance at all ESS sessions, the Symposium, and 3-day conference registration (Wednesday to Friday). This package costs €600 for members and €650 for non-members.

The Symposium

This event is open to members and non-members. The registration fee for non-members is €350 and includes attendance, conference materials, and all refreshments for the symposium day.

Administration fees as specified above also apply to changes to or cancellation of registration for these packages.

Introduction to Medical Writing seminar

This event is open to the public and is free of charge. Attendees are asked to register in advance and should note that refreshments are available only to paying conference delegates. If after you have registered you decide not to attend this event, please let us know so that we can offer the place to someone else.

Social events

Details and charges for all social events are in the social events section of the brochure (pages 23).

Payments

At the time of registration, delegates may choose between immediate payment by credit card or to be invoiced. Invoices are to be settled by bank transfer in euros. All fees are payable in advance. Full payment is due by Tuesday 10 May 2016. If payment has not been received, EMWA reserves the right to request payment on-site at the late registration rate.

Conference overview

For full workshop abstracts and leader profiles please visit the online conference planner.

Online conference planner

Note: Almost all for-credit workshops have a pre-workshop assignment or pre-workshop reading, and **you will have to download this from the EMWA website.** All for-credit workshops have an assessed post-workshop assignment you will receive from the workshop leader. Seminars do not have pre-workshop or post-workshop assignments. See page 5 for more information about how to gain EPDP credits.

Tuesday 10 May

16:30 onwards	EMWA Registration desk opens
17:30–19:00	Opening Session and Welcome Lecture
	Servus Bavaria: the land of beer, crazy kings and medical writers. Beatrix Doerr introduces you to Bavaria, its history and the peculiarities of its inhabitants.
	Learning from Accidents: Integration of Technical, Medical and Psychological Perspectives in the Context of Accident Research Stefani Weber (AARU – Audi Accident Research Unit)
19:00–20:30	Networking Event

Wednesday 11 May

07:00–07:30	Easy Morning Yoga session
08:45–12:15 DDA20	Risk Management Plans: Challenges and Insights (Drug Development – Advanced) Tiziana von Bruchhausen (Boehringer Ingelheim Pharma GmbH & Co.KG)
08:45–12:15 PTF8	Cross-Cultural Communication (Professional Techniques – Foundation) Kari Skinningsrud (Limwric as)
08:45–12:15 MCF21	Promotional Medical Writing: The Dark Side (Medical Communication – Foundation) Sarah Chen (Publicis Life Brands International)
08:45–11:45 DDF2	The Investigator's Brochure (Drug Development – Foundation) Barry Drees (Trilogy Writing & Consulting GmbH)
08:45–16:30 LWF13+14	Editing and Proofreading Essentials (Double Workshop) (Language and Writing – Foundation) Barbara Grossman (Hawkeye Medical) Marian Hodges (National Institute for Health and Care Excellence)
08:45–11:45 PTF5	Medical Writing and Quality Control of Documents Entering the Public Domain: Manuscripts and Abstracts (Professional Techniques – Foundation) Alison McIntosh (ICON Clinical Research (UK) Ltd)
08:45–11:45 PTF23	Subgroup Analysis (Professional Techniques – Foundation) Cheryl Roberts (BioMarim Pharmaceutical Inc)

08:45–12:15 MCF17	Using Writing Guidelines for Manuscripts (Medical Communication – Foundation) Andrea Rossi (Eli Lilly Italia)
08:45–12:15 DDA1a	Writing Global Submission Dossiers using the Common Technical Document (Drug Development – Advanced) James Visanji (Trilogy Writing & Consulting GmbH)
08:45–12:00	**ESS Session 1** **The Impact of Clinical Trial Data Disclosure on Trial-related Documents: Redaction Requirements and Future Document Structure** Tracy Farrow (PPD) **Saying Goodbye to Manual Referencing: Embracing EndNote** Margaret Mathes (RTI Health Solutions)
10:00–10:45	Refreshment break and exhibition viewing
11:45–13:30	Lunch
13:30–17:00 LWA12	Master Class: Taxonomic Analysis of Medical Writing (Language and Writing – Advanced) Michael L Schneir (University of Southern California School of Dentistry)
13:30–16:30 LWF9	Summarising (Language and Writing – Foundation) Wendy Kingdom (Wendy Kingdom Ltd)
13:30–16:30 PTF22	Managing the Clinical Study Protocol Writing Process (Professional Techniques – Foundation) Abraham-Fred Shevack (Freelance)
13:30–17:00 DDA14a	Periodic Benefit-Risk Evaluation Reports (Drug Development – Advanced) Alison Rapley (Freelance)
13:30–17:00 PTA2	Do More with Less Faster: Project Management for Biomedical Communications (Professional Techniques – Advanced) Art Gertel (MedSciCom, LLC)
13:30–16:30 MCF1a	Introduction to Manuscript Writing (Medical Communications – Foundation) Julia Forjanic Klapproth (Trilogy Writing & Consulting GmbH)
13:30–17:00 DDA3	The CTD Clinical Summary (Drug Development – Advanced) Debbie Jordan (Debbie Jordan Ltd)
13:30–16:30 MCF20	Resources for Medical Translators (Medical Communication – Foundation) Andrea Palluch (Inpharmedia) Laurence Auffret (CINETIQUE Translations)

13:30–16:45 ESS Session 2

Working with India as a Partner for Medical Writing – Expectations and Best Practices
Joanne Hilton (Kinapse)

How to Build a Medical Writing Group in the Asia Pacific Region, Focusing on China and Japan
Roselynn Tien (Parexel)

14:45–15:30 Refreshment break and exhibition viewing

17:15–18:15 Annual Meeting

The official EMWA administrative meeting takes place once a year at the Spring Conference. In addition to formal matters of association business that require consultation with the membership (which are kept to a minimum to maximise time for other matters), this is the opportunity for members to make their opinions heard on a formal level. If you have any ideas you want to make known or want your voice to be heard, this is the place to do it. To request items to be put on the agenda, contact Lynne Fletcher at info@emwa.org. The Annual Meeting also marks the beginning and end of the President's term of office and those of some other officers, following the preconference electronic elections. It is one of the few times that the Executive Committee and the membership come together in person, so please come along and use this opportunity to put names to faces and make your presence felt. We need you and want to hear what you have to say!

19:00–23:00 EMWA Spring Dinner and Dance
See page 23 for further details

Thursday 12 May

07:00–07:30 Easy Morning Yoga session

08:00–08:30 Getting your foot in the door: how to build experience to get a first medical writing job
YGMW Phil Leventhal (All4IT France)

new

Getting a first medical writing job is difficult because there are very few educational opportunities and because employers always want experience. This situation creates vicious circle where it's seemingly impossible to get experience without already having some. Phil Leventhal, Editor-in-Chief of Medical Writing and member of EMWA's Executive Committee, will share how he got a foot in the door, and he will discuss ideas for building writing experience needed to land a first job in medical writing. This seminar is free of charge.

08:00–08:30 How to work more efficiently in and on your business
XSSKW Kathryn White (Cathean Limited Medical Writing Consultancy)

This seminar is free of charge and is primarily for freelance medical writers who have to juggle client demands with those of their business. Many freelancers struggle to find time to manage their personal and business needs whilst meeting client demands and deadlines. This seminar will introduce and explore the concepts of working 'on your business' as well as 'in your business', describing processes, systems and practices which may be implemented to help freelancers manage their business more efficiently while managing their clients more effectively.

09:00–17:00 **4th EMWA Symposium: Scientific and Medical Communication Today**
See page 19 for full programme and details

08:45–16:30 Clinical Study Reports – Mastering the Essential Skills (double Workshop)
DDF33+34a (Drug Development – Foundation)
Sarah Tilley (Scinopsis)
Gaële Ducher (Scinopsis)

08:45–12:15 DDA6	Advanced Clinical Study Design (Drug Development – Advanced) Rosemary Bischoff (ClinWrite)
08:45–11:45 MSF9	The Basics of Genetics for Medical Writers (Medical Science – Foundation) John Carpenter (John Carpenter Medical Communications)
09:00–11:30 XSSHB	Introduction to Medical Writing (Short Seminar – Not for credit) Helen Baldwin (Scinopsis)

This seminar is provided free of charge and is aimed at those considering a career in medical writing. It is open to conference delegates and members of the general public. It will also be interesting to those who have recently joined the profession who would like to know more. In addition to a presentation covering all aspects of medical writing, the seminar leader will act as a facilitator to optimise exchange of experience between participants, as well as providing insight based on her expertise in this area.

The aim is to provide information on the following:

- Definition of medical writing and its different categories
- Role of the medical writer throughout the life-cycle of a pharmaceutical product
- Explanation of the different types of documents that we write with detailed information on some of the most common (e.g. clinical study protocols and reports, investigator brochures, CTDs, manuscripts, posters)
- Timelines and project management
- Finding a job as a medical writer (qualities and qualifications required), types of companies that employ medical writers, recruitment process, working as a freelancer
- Training and networking for medical writers

Members of the public who wish to attend the seminar should approach the EMWA Staff at the Conference Registration Desk who will issue them with a temporary badge and direct them to the seminar room.

10:00–10:45	Refreshment break and exhibition viewing
11:45–13:30	Lunch
12:45–1:15 RPDSIG	CORE Reference and RPDSIG launch
13:30–17:00 LWF4a	Medical English – Common Problem Areas for Non-native Speakers (Language and Writing – Foundation) Susanne Geercken (Pfizer Pharma GmbH) Alistair Reeves (Ascribe Medical Writing & Translation)
13:30–16:30 MSF3	Basics of Epidemiology for Medical Communicators (Medical Science – Foundation) Rita Wellens (Wellens Clinical Research Consulting)
14:45–15:30	Refreshment break and exhibition viewing
17:15–18:15	EMWA Editorial Board Meeting
17:15–18:45	**Freelance Business Forum** (Discussion Forum – Not for credit)

This is an open forum for freelance medical writers. The aim is to share experience of dilemmas and solutions. It is an opportunity to find out how other freelancers approach the business of medical writing, to pass on any tips you might have for newcomers, and find out what freelance writers can do for, and expect from, EMWA.

17:15–18:45 **Internship Forum**

This pilot initiative will run as a networking forum for people new to medical communications who want to get into the business and are interested in an intern position. Internships can provide a great way to gain experience and explore different career paths. This open forum aims to bring together up to 10 companies offering internship places with prospective medical writers wanting to get into the industry.

19:00 Social events. For further details, see page 23

Friday 13 May

07:00–07:30 Easy Morning Yoga session

08:45–11:45
DDF4
The Patient Information Leaflet
(Drug Development – Foundation)
Wendy Kingdom (Wendy Kingdom Ltd)

08:45–11:45
MCF13
Management of Translation Projects
(Medical Communications – Foundation)
Laurence Auffret (CINETIQUE Translations)

08:45–11:45
DDF32
Introduction to Pharmacovigilance Writing
(Drug Development – Foundation)
Tiziana von Bruchhausen (Boehringer Ingelheim Pharma GmbH & Co.KG)
Sven Schirp (Boehringer Ingelheim Pharma GmbH & Co. KG)

08:45–12:15
PTA10
Effective Reporting of Scales, Questionnaires and VAS
(Professional Techniques – Advanced)
Thomas Wagner (Merck KGaA)

08:45–11:45
DDF36
The Impact of Clinical Trial Disclosure on Trial-related Documents
(Drug Development – Foundation)
Tracy Farrow (PPD)
Christopher Marshallsay (Grünenthal GmbH)

08:45–12:15
PTA3d
Slippery Slopes: Survival Analysis
(Professional Techniques – Advanced)
Thomas Schindler (Boehringer Ingelheim Pharma GmbH & Co.KG)
Elisabeth Kuhn (Boehringer Ingelheim Pharma GmbH & Co.KG)

08:45–12:15
MCF16
Publication Ethics
(Medical Communication – Foundation)
Julia Donnelly (Julia Donnelly Solutions)
Elise Langdon-Neuner (Freelance)

08:45–12:15
MSF4a
Pharmacogenomics
(Medical Science – Foundation)
Andrea Palluch (Inpharmedia)

08:45–11:45 PTF25	Patient Registries as a Source of Medical Information (Professional Techniques – Foundation) Maria Kołtowska-Häggström (Proper Medical Writing) Adam Jacobs (Premier Research)	new
08:45–12:00	**ESS Session 3** **Artificial Intelligence and Automated Authoring – Current State of Affairs** Keith Kleeman (Clingenuity) **Medical Writing for Studies with Adaptive Design** Susanne Herzig (ICON)	
09:00–17:00	EMWA Executive Committee meeting	
10:00–10:45	Refreshment break and exhibition viewing	
11:45–13:30	Lunch	
12:45–13:15	Update on Clinical Trial Disclosure Kathy Thomas-Urban (Medical and Scientific Writing and Publication Services)	
13:30–17:00 LWA14	The Medical Journal Article: Section-Specific Distractions (Language and Writing – Advanced) Michael L Schneir (University of Southern California School of Dentistry)	
13:30–17:00 LWA5a	Master Class: Editing English Texts Originating from Non-Native Speakers (Language and Writing – Advanced) Rosemary Bischoff (Clinwrite) Alistair Reeves (Ascribe Medical Writing & Translation)	
13:30–16:30 PTF21	Health-Related Quality of Life (Professional Techniques – Foundation) Claire Gudex (University of Southern Denmark)	
13:30–17:00 DDA16	Clinical Trial Disclosure for Medical Writers: Results Posting (Drug Development – Advanced) Uma Swaminathan (GlaxoSmithKline Vaccines) Tatjana Poplazarova (GlaxoSmithKline Biologicals	
13:30–16:30 DDF35	Introduction to Writing about Efficacy (Drug Development – Foundation) Helen Bridge (Accovion Ltd)	new
13:30–16:30 MSF6	Why Do Drugs and Medicines Have Adverse Effects? (Medical Science – Foundation) John Carpenter (John Carpenter Medical Communications)	
13:30–17:00 DDF26	Introduction to Writing for Medical Devices (Drug Development – Foundation) Claudia Frumento (ICiMT International Consulting in Medicine and Technology)	

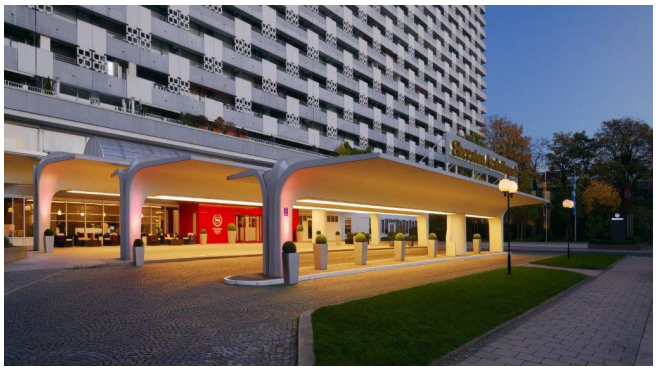
13:30–16:30 MSF11	Fundamentals of Haematology (Medical Science – Foundation) Robbert van der Voort (Vision Medical Communications)
13:30–17:00 MCA3a	Systematic Reviews (Medical Communication – Advanced) Katharina Biester (Institute for Quality and Efficiency in Health Care)
13:30–17:00 DDA7	Serving Two Masters: Comparing and Contrasting US and EU Regulatory Submissions and Processes (Drug Development – Advanced) Susan Bhatti (Merck Serono) Art Gertel (MedSciCom, LLC)
14:45–15:30	Refreshment break and exhibition viewing
17:15-17:45	PV SIG meeting update Chair: Lisa Chamberlain James. Key contributors – Rohit Pushparajan, Tiziana von Bruchhausen
19:00	Social events – for further details see page 23

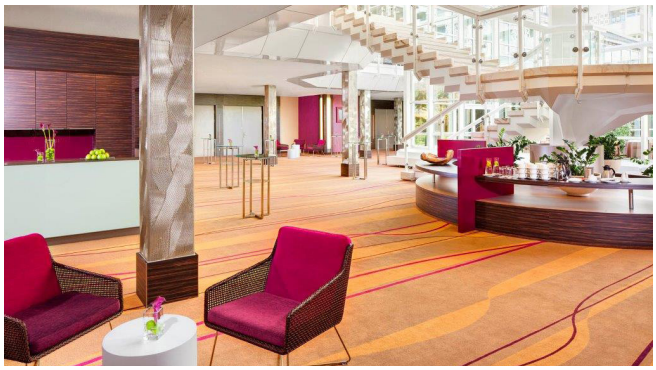
Saturday 14 May

07:00–07:30	Easy Morning Yoga session
08:45–11:45 PTF19	An Introduction to Marketing for Medical Writers (Professional Techniques – Foundation) Diarmuid De Faoite (AO Documentation & Publishing Foundation)
08:45–11:45 PTF13	Critical Appraisal of Medical Literature (Professional Techniques – Foundation) Adam Jacobs (Premier Research)
08:45–11:45 MCF5	Overcoming Publication Hurdles: Dealing with Biomedical Journals (Medical Communication – Foundation) Elise Langdon-Neuner (Freelance)
08:45–12:15 PTF20	Introduction to Health Economics (Professional Techniques – Foundation) Stuart Mealing (Oxford Outcomes ICON Plc)
08:45–12:15 LWF8	Sharpen Up Your Writing Skills (Language and Writing – Foundation) Jo Whelan (Textpharm Ltd)
08:45–11:45 MCF3	Creating an Impact with Posters (Medical Communication – Foundation) Julia Donnelly (Julia Donnelly Solutions)

08:45–11:45 DDF6b	From Protocol to Study Report: What's In-between? (Drug Development – Foundation) Franziska Pirkl (Kantar Health)
08:45–11:45 DDF29	Protocol Amendments (Drug Development – Foundation) Walther Seiler (Bayer Pharma AG)
08:45–12:15 DDA18	Medical Writing for Healthy Volunteer Studies (Drug Development – Advanced) Anne McDonough (McDonough Clinical Research Ltd)
08:45–12:15 DDA15a	Development Safety Update Reports (Drug Development – Advanced) Sarah Choudhury (Parexel International)
08:45–12:45	EPDC Meeting
10:00–10:45	Refreshment break
11:45–13:30	Lunch
13:30	Delegate departure

Conference venue and accommodation





Sheraton Munich Arabellapark Hotel
Arabellastrasse 5, 81925 Munich, Germany
Tel: +49 89 92320
Fax: +49 89 9232 4449

Accommodation is offered at a rate of €159 per night for single occupancy including breakfast. This rate is available to EMWA delegates until 25 March 2016 after which the hotel reserves the right to offer accommodation at the current rate.

Click on the link below to book your room at the Conference Hotel.

EMWA Conference accommodation booking

Getting to the Sheraton Munich Arabellapark Hotel from Munich Airport

Take the S1/S8 S-Bahn (city train) line towards the city centre, and change onto the U4 metro at Karlsplatz (Stachus) in the direction of Arabellapark. Get off at the terminus Arabellapark, and leave the metro station in the direction of Rosenkavalierplatz. Follow the signs for the 'Sheraton Arabellapark Hotel Munich'.

A taxi from the airport takes around 45 minutes and will cost approximately €65.

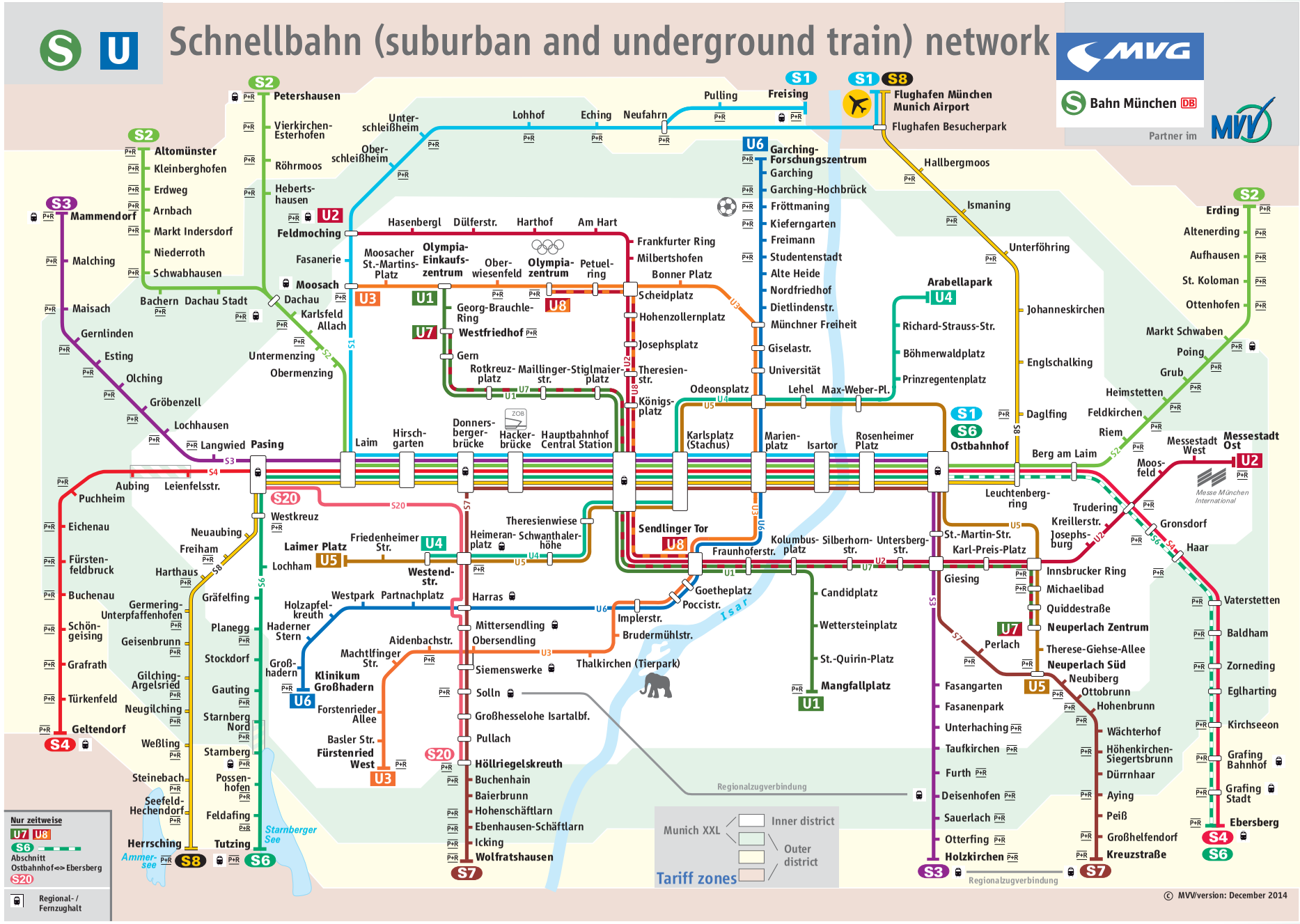
Underground parking is available at the hotel. Arrival via Englschalkinger Strasse and Rosenkavaliersplatz. Price per 24 hours is €20

Accommodation – alternative hotels

We have identified a number of hotels in different price categories within walking distance of the Conference Hotel. Please note that EMWA does not offer a recommendation for the accommodation quality or customer service for these alternative hotels.

Alternative accommodation booking

Schnellbahn (suburban and underground train) network



4th EMWA Symposium
Scientific and Medical Communication Today

The Symposium day will focus on the ever-changing field of medical communications and the importance of medical writers as medical communicators. The evolved role from regulatory, medical and scientific writer to the role of medical communicator, specialising in a specific therapeutic area or field of communication will be explored with reference to:

- What 'communication' actually means
- The different ways of communicating medical issues effectively
- How to 'communicate' with the patient, parent and caregiver
- Scientific communication and non-scientific media
- Effective means of translating scientific communications
- Regulator (EMA) perspective on how to communicate medical research and findings
- Industry-driven research and its communication to healthcare professionals and non-medical audiences
- Medical communications agencies – in medias res ('in the thick of it')
- Publishing scientific and clinical research – past, present and future trends

Expert Seminar Series

The EMWA Expert Seminar Series (ESS) is for experienced medical writers, heads of medical writing departments, and industry leaders from other disciplines who want to learn about the latest developments affecting the medical writing industry and play a role in shaping the world of medical writing.

Wednesday 11 May

ESS Session 1

08:45–10:15 **The Impact of Clinical Trial Data Disclosure on Trial-related Documents: Redaction Requirements and Future Document Structure**
Tracy Farrow (PPD)

This presentation, first given at the DIA 28th Annual EuroMeeting in Hamburg, 6–8 April 2016, will explore the impact of clinical trial disclosure and data transparency on clinical trial documentation, focussing primarily on the protocol and clinical study report (CSR). The effect of the evolving regulatory framework on balancing patient privacy and data transparency when redacting commercially confidential information (CCI) and personal protected information (PPI) will be explored. The potential impact of clinical trial disclosure will be discussed, including structural and content considerations for protocols, CSRs, and other relevant clinical trial documentation.

An outline of regulatory and data privacy guidance will contextualise the topic of redaction and data masking whilst maintaining transparency for the purpose of clinical trial disclosure. CCI, the reasons for redaction, the legal basis of PPI, and strategies for mitigating risk of identification will be discussed. The impact of these concepts on protocol design and CSR content and structure – both now and in the future – will be explored.

The aspects of clinical trial disclosure most relevant for medical writers, including newly required documents and emerging challenges with respect to protocol and CSR writing, will be highlighted.

10:30–12:00 **Saying Goodbye to Manual Referencing: Transitioning to EndNote**
Margaret Mathes (RTI Health Solutions)

EndNote is one brand of reference management software that facilitates efficient and accurate researching, writing, and publishing of documents. However, adopting referencing software may seem like a daunting task to writers who have never used it. This session will give writers a basic understanding of how to use EndNote. It will include instructions for performing a literature search, reviewing references, and organising references. The speaker will also demonstrate how to use EndNote's 'cite while you write' function to insert citations into a document and how to update the bibliography. Finally, the session will discuss how multiple writers and editors can work together from the same EndNote library even when writers and editors work from different locations; this is achieved using EndNote's library sharing feature. The panel will introduce perspectives on alternative available reference management software brands.

ESS Session 2

13:30–15:00 **Working with India as a Partner for Medical Writing – Expectations and Best Practices**
Joanne Hilton (Kinapse)

Medical writing has gained considerable interest from colleagues in India, as evident from their attendance at recent EMWA events, the formation of medical writing associations in India (such as AIMWA and IMWA), and an increased interest in the EMWA website (India has the 3rd highest number of hits, after the UK and Germany).

Increasing numbers of pharmaceutical companies and contract research organisations work with Indian companies either as partners or as part of their business working models.

The session will discuss the advantages associated with partnering with India, the challenges and ways of overcoming them, and will include the following discussion points:

- Reasons for partnering with India
- The different working models
- Prerequisites for a good partnership. Is it a suitable option for every company?

- Cultural differences to be aware of and their impact on working models
- Best practices for a successful partnership.

15:15–16:45 **How to Build a Medical Writing Group in the Asia Pacific Region, Focusing on China and Japan**
Roselynn Tien (Parexel)

This presentation will focus on how to achieve goals to create and develop a medical writing team in the Asia Pacific Region (AP) with specific emphasis on achieving global alignment using training and standard operating procedures, hiring ahead of the curve, supporting global and local businesses, and increasing the awareness about regulatory medical writing in the AP.

Based on the session leader's experience, goals are achieved by working closely with human resources to identify medical writers with the appropriate skills, such as hiring those who are trilingual (i.e. able to communicate in English, Chinese and Japanese), who are able to communicate well with customers and colleagues, and who can learn 'on-the-job' and via internal or external development programmes.

The session will look at the different paths available to achieve these goals and consider the pros and cons of having medical writers in multiple locations. The session will also explore how to assure efficiency by matching the complexity of the documents with the experience of each medical writer, and providing the necessary support from line and project management and mentors. Those involved in building a medical writing group in the AP should aim to build a high performance culture where medical writers can say what they think, own a problem and find a solution, provide great customer service, and contribute to a profitable business.

Friday 13 May

ESS Session 3

08:45–10:15 **Artificial Intelligence and Automated Authoring – Current State of Affairs**
Keith Kleeman (Clingenuity)

Employing information 're-use' and artificial intelligence (AI) to produce study protocols and clinical study reports (CSRs) might sound like science fiction, but for some medical writers it is science fact.

A variety of software tools exist to aid the regulatory writer, such as word processors, structured authoring systems, and now AI. This session provides a comprehensive overview of automated authoring using AI. Attention is given to natural language recognition and processing which can be used every day, and which makes the concept of AI automated authoring accessible to the layperson.

In addition, the session will compare AI automated authoring with structured content management and modular authoring concepts. This will allow attendees to differentiate between the automation tools currently available in the marketplace and understand the practicality of each.

Real life examples and metrics of using AI automated authoring, including efficiency gains, will be given.

10:30–12:00 **Medical Writing for Studies with Adaptive Design**
Susanne Herzig (ICON)

There are many reasons why clinical trials can fail to demonstrate the expected outcomes. Once regulatory authorities and ethics committees approve study protocols, there is limited opportunity to accommodate changes that may emerge while the study is ongoing. Any future correction of study design – due to, for example, incorrect specification of the treatment effect or variability in effect, baseline factors that show strong influence on the study endpoints, or eligibility criteria that do not translate into the appropriate population – is regarded as potentially introducing bias. The benefit of having an adaptive design is that it allows the mitigation of such risks by prospectively planning for optional modifications of one or several elements of the study based on interim results. Moreover, the framework of adaptive designs allows for early termination of a study perhaps because efficacy has been shown early, or because of futility. This flexibility fosters progress in drug development by potentially saving time during a drug development programme and may require fewer subjects to be exposed to an investigational drug to achieve robust and

meaningful results. Both the European Medicines Agency and the Food and Drug Administration have acknowledged these methods in several publications.

This presentation covers the basics on how to define and describe adaptive design features in the study protocol. In addition, considerations are given to the wording of protocol amendments. The session leader will describe the basic principles for information flow between medical writers and blinded and unblinded study teams and investigators. Finally, potential discussion points often raised during the identification, description and presentation of the final results in the CSR will be reviewed, including examples of typical and unexpected results.

Although medical writers routinely participate in discussions about study design and interpretation of results, decisions are often made by other team members or by external experts. Nonetheless, precise descriptions in the protocol, any protocol amendment or in the CSR are essential to maintain study integrity and the acceptability of the results. Therefore, the skills of the medical writer are of central importance for the overall success of development programmes that include adaptive clinical trials.

Social events

If you miss the Happy Bavarians at the Spring Dinner and Dance you will regret it!

Spring Dinner and Dance

Wednesday 11 May from 20:00 (4 hours)
€49 per person including all food and drinks

Augustiner Keller

An evening out in Munich would not be complete without the chance to dance to traditional Bavarian music and enjoy a real-life Bavarian spectacle with cow-bell ringing, an alpine horn, a typical Bavarian clock-dance, whip-cracking, slap-dancing, and the original wood-chopper dance with real axes and saws. To ensure that as many of you as possible have a chance to join in, EMWA is subsidising this true Bavarian entertainment that you just cannot afford to miss.

Social events

Bavarian Beer Tour
Thursday 12 May and Friday 13 May from 19:00 (3 hours, leaving from the hotel)
€35 per person
Maximum per tour of 20

We'll tell you how beer is brewed and fill you in on the fascinating story of German brewing – a story as old as Germany itself. For as long as there have been Germans, there has been beer. From the ancient tribal Hausfrauen brew-women and the great monastic breweries of the middle ages, to the revered Reinheitsgebot (Purity Law) of 1516 – which continues to be the measure of excellence in brewing today – the world has looked to Germany to set the standards of what a cool drink of great beer should be. And Germany looks to Munich. We'll show you why.

We'll inform you of the different types of beer available and let you sample them for yourself. And we'll introduce you to the best traditional Bavarian food in all its variety – Weisswurst, dumplings, roast pork and more. Don't eat before the tour!

This is not a pub crawl. This is a tour through the rich history and culture of Bavarian beer and food

Munich Walking Tour
Thursday 12 May from 19:30 (about 2 hours, leaving from the hotel)
€17 per person including transport to and from Marienplatz
Maximum per tour of 20

A 2-hour walking tour including the highlights of the old town, such as the Marienplatz, Odeonsplatz, Viktualienmarkt, Hofbräuhaus, Frauenkirche, giving a great insight into historic and modern Munich.

Social events

Traditional Bavarian Dancing
Thursday 12 May from 19:30 (2 hours, based at the hotel)
€30 per person
Maximum 15 participants

Workshop for Bavarian folk dance with Bavarian polka, Bavarian waltz, traditional dancing accompanied by traditional Bavarian folk music.

Munich Bicycle Tour
Friday 13 May from 19:00 (3 hours, leaving from the hotel)
€30 per person including transport to and from Marienplatz
Maximum per tour of 20

The tour starts on Marienplatz. We take the bikes and ride through the city to the English Garden with regular stops to learn about the history of Munich. The tour ends in the beer garden at the Chinese Tower in the English Garden.

Speaker profiles

Tracy Farrow
PPD
Tracy is currently Senior Director, Medical Writing for PPD, has more than 25 years of Biomedical Science experience. Before PPD she worked for ClinTec International as Manager, Medical Writing Services; 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 programme. She attained her 2.1 (Hons) G.I.Biol in Biochemistry in 1993 after gaining two Higher National Certificates in Haematology and Chemistry. 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 public disclosure of clinical-regulatory documentation.

Susanne Herzig
ICON Clinical Research
Susanne is a physician who worked in hospitals in internal medicine and surgery before joining pharmaceutical research. For over 20 years, she has worked for contract research organisations in project management, safety and medical writing. She is currently a senior medical writer at ICON Clinical Research in Germany. In her current position, Susanne has been involved with developing adaptive study designs for various indications, including writing of study protocols and informed consent forms (ICFs), designing case report forms, advising study teams during the clinical phase of the study on medical and statistical aspects, compiling updated ICFs and protocol amendments, where necessary, based on the interim results, up to writing final reports that take into account the results of interim analyses and the decisions of sponsors that were based on these results and the recommendations of expert and independent advisory committees. Moreover, Susanne has prepared and moderated meetings with regulatory authorities during which sponsors suggested adaptive designs. Based on comments from authorities, she has been involved in re-designing adaptive protocols and in meetings to explain and defend the rationale and benefit for using adaptive designs.

Joanne Hilton
Kinapse
Joanne's medical writing experience spans over 15 years and includes working for pharmaceutical and medical communications companies. She is the Global Head of Medical Writing at Kinapse and over the past decade has built a team of approximately 100 staff in India, the EU and US. Kinapse delivers medical writing solutions through a proven 'blended resourcing' model. Within the blended model, lead writers based in the UK/US collaborate closely with writers in India throughout a document lifecycle to supply high quality deliverables to the client on time and within budget. Joanne holds a PhD in Medicine from the University of Melbourne, Australia.

Keith Kleeman
ClinGenuity
Keith is the Founder and CEO of ClinGenuity, the only artificial intelligence, automated authoring and redaction tool in the industry. He was also the founder and CEO of Medical Communication Consultants, a manual medical writing firm of over 100 expert writers that merged with ClinGenuity in May 2014. Keith has been involved in medical writing for more than 15 years, both as an in house writer for major pharmaceutical companies, and as an external vendor. In December 2014, Synchrogenix, a Certara Company, acquired ClinGenuity. Keith is now President of Synchrogenix, and oversees all of the ClinGenuity artificial intelligence offerings.

Phil Leventhal
All4IT France
Phil is currently a scientific writer at 4Clinics France in where he specialises in publications writing. He has more than 10 years' experience as a medical writer, has authored and edited hundreds of peer-reviewed articles, and has worked extensively with, and trained, non-native English speakers in scientific writing. Before transitioning to scientific writing, Phil worked for 15 years in the United States as a biochemist and cell biologist in academic and pharmaceutical research. In addition to his work for 4Clinics France, Phil is currently Editor-in-Chief of EMWA's official journal, 'Medical Writing'.

Margaret Mathes
RTI Health Solutions
Margaret is a medical editor at RTI Health Solutions, where she supports the organisation's Market Access and Outcomes Strategy (MAOS) and Health Preference Assessment groups. The MAOS team is composed of writers in the United States and the United Kingdom and specialises in producing global value dossiers, Academy of Managed Care Pharmacy dossiers, and systematic literature reviews; many of these documents include more than 200 references. Until mid-2014, all references in these documents were cited manually, and a reference list was produced and edited manually. In an effort to streamline this process and to meet client requests for reference databases, Margaret learned to use EndNote software, led the revision of an existing best practices guide, created training guides specifically for writers and editors, and conducted training sessions for the organisation.

Margaret has more than 13 years of experience as an editor in academic and scientific environments. Her past experience includes serving as the production manager at AlphaMed Press, where she oversaw the production, editing, and online and print publication of two journals: Stem Cells and The Oncologist.

Kathy B Thomas-Urban
Medical & Scientific Writing & Publication Services
Kathy is an independent consultant with an extensive background in the area of Clinical Trial Disclosure. She has followed the development and consolidation of the law in the US (FDAAA 2007, ClinicalTrials.gov platform) and is currently observing the developments on this topic in the European Union and European Economic Area (EU Clinical Trial Regulation 2014, EudraCT platform). She has a broad knowledge of and experience in preparing entries for registries, and developing internal guidelines and processes to assure compliance with clinical trial disclosure policies. She is an active member of professional international work groups on this topic. Kathy is also a medical writer, with more than 18 years of experience in the academic and pharmaceutical industry setting, preparing a wide range of clinical and drug safety documents for modules of the Common Technical Document for regulatory submissions, investigator's brochures, aggregate drug safety documents (PSUR, DSUR), manuscripts for peer-review journals, abstracts, posters, and slide presentations for international scientific and medical conferences. Kathy served as the Head of Medical Writing from 2001-2007 at Altana Pharma AG, Konstanz, Germany. She lives in southern Germany and speaks English, German, Czech, and Slovak fluently.

Roselynn Tien
Parexel
Roselynn Tien's medical writing career started in Germany following the completion of her PhD at the Christian Albrecht University in Kiel. For the past 15 years, she has worked in various clinical research environments in contract research organisations, pharmaceutical companies and medical communication agencies. Her responsibilities have included scientific and medical writing for preclinical, clinical (phase 1 4) and pos marketing studies, business development, event organisation, exhibition design and build, publication coordination and people development. Over the past 5 years, Roselynn has successfully built a team of 14 medical writers and managers across Singapore, China and Japan covering trilingual regulatory document

submissions. As Head of Global Resource Management for Medical Writing Services at Parexel, she is responsible for pre-award resource forecasting and post award resource management of over 120 medical writers.

Kathryn White

Cathean Limited Medical Writing Consultancy

Kathryn worked as a clinical research manager and medical writer in the pharmaceutical industry for over 15 years, before embarking on a freelance career. Since becoming a freelancer, Kathryn has successfully worked alongside international business coach, Elaine Bailey, to improve her own work-life balance and business processes, systems and practices. Kathryn has experienced first-hand the significant benefits of coaching; the strategies she has implemented have positively impacted her work-life balance and business success. In summer 2012, Kathryn initiated the first UK medical writers' retreat for freelancers, which was well attended and received very positive feedback. She continues to organise these retreats and has published articles on the concepts of working in and on your business. Kathryn has been a member of EMWA since 2010 and has co-edited the Out On Our Own section of the Medical Writing journal, co-hosted the Freelance Business Forum and supports the EMWA webinar team.

Future events

43rd EMWA Conference

3–5 November 2016
The Sheraton Hotel, Brussels, Belgium

44th EMWA Conference

2–6 May 2017
The International Conference Centre,
Birmingham, England

45th EMWA Conference

2–4 November 2017
Hotel Cascais Miragem, Cascais, Lisbon, Portugal

43rd EMWA Conference

EUROPEAN MEDICAL WRITERS ASSOCIATION

3–5 November 2016

The Sheraton Hotel, Brussels, Belgium

www.emwa.org