39th EMWA Conference

EUROPEAN
MEDICAL
WRITERS
ASSOCIATION

6–8 November 2014

The Grand Hotel Mediterraneo, Florence, Italy

www.emwa.org

EUROPEAN MEDICAL WRITERS ASSOCIATION

Contents

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Available on the App Store

GET IT ON Google play

Message from the

EMWA Executive Committee

Welcome to the 39th EMWA Conference in the beautiful city of Florence. Our lovely venue, the Grand Hotel Mediterraneo, is perfectly located to allow you to enjoy the city if you manage to find any time to escape from our packed Autumn programme.

This year EMWA is offering 28 training workshops, 20 at foundation and 8 at advanced level, covering a broad range of topics. Following a successful trial-run in Barcelona last year, we have now formally introduced four workshop sessions, allowing delegates to obtain up to four credits at an Autumn meeting. Now members can obtain an EMWA certificate after attending just two EMWA conferences.

Whether or not you are aiming for an EMWA certificate, our diverse programme offers opportunities to learn about different areas of our profession, develop new skills, and keep up-to-date with recent developments in medical writing. Our conference is also a unique chance to interact with fellow professionals, network within our industry, and share ideas and experiences.

If you are attending an EMWA conference for the first time, please be reassured that you will be welcomed by many friendly faces. We have opportunities for networking at mealtimes, breaks, organised events, and during interactive exercises in many of the workshops. We will be especially pleased to see you at the Opening Event and Networking Reception on the first evening.

Florence has to be one of the 'must visit' European cities for most people, combining art, architecture, history and, we hope, pleasant Autumn temperatures. You may wish to extend your stay beyond the conference to fully enjoy the treasures on offer and wonderful Italian hospitality.

We are grateful to our dedicated and enthusiastic workshop leaders, who volunteer their time and services to deliver such high-quality training. We also thank the conference team, and, of course, Head Office. Together, we once again aim to deliver a conference to be proud of.

EUROPEAN MEDICAL WRITERS ASSOCIATION

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 have both a pre-workshop exercise or pre-reading, and an assessed post-workshop assessment. 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.

By gaining credit for eight workshops, participants can obtain an EMWA professional development certificate, as described below. Those not wanting credits can attend workshops without doing the assignments, and will 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 recap the basics of the subject for attendees who do not fit the profile in the workshop description.

Note: All workshops except not-for-credit workshops and seminars have pre- and post-workshop assignments.

Gaining EPDP credits

To receive credit for a workshop, you must:

- Download your pre-workshop assignments from the Members' only area of the EMWA website after registering for the conference.
- Complete the pre-workshop assignment (usually up to 2 hours), and submit it to the workshop leader by the deadline given, if applicable.
- Attend the workshop.
- Complete the post-workshop assignment (up to 3 hours) to a satisfactory standard, and submit it by the deadline given.

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 the issuing of certificates. Members who have previously paid the EPDP enrolment fee will be exempt from this for the 5 years from their date of enrolment.

EMWA certificates

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

There are two levels of certificate: Foundation and Advanced.

An EMWA Foundation Certificate is awarded for eight credits from foundation workshops as follows:

- At least five workshops in a single subject area to qualify for a specialised certificate in that option.
- Workshops in at least two subject areas but no more than four workshops per area for a multidisciplinary certificate.

Members may obtain more than one specialised Foundation Certificate after completing the appropriate requirements for each certificate.

An EMWA Advanced Certificate is awarded for credits in any eight advanced workshops. A Foundation Certificate is not a pre-requisite for an Advanced 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 (www.emwa.org).

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

Conference registration is available to members of the European Medical Writers Association (EMWA). Members and new members can register online via the EMWA website (www.emwa.org). EMWA Head Office can be contacted by e-mail (info@emwa.org) or by telephone (+44 (0)1625 644 534) for help with membership or conference registration queries.

Note: All fees in sterling (£) below are for guidance only and will vary according to the euro exchange rate at the time of payment.

Registration fees

	Members	New members in Europe	New members outside Europe	
Early Registration	€200 £158	€330 £261	€345	Before midnight on 3 October
Regular Registration	€300 £237	€430 £340	€445	4 October – midnight on 24 October
Late/Onsite Registration	€400 £317	€530 £419	€545	25 October onwards

The registration fee includes the Opening Event and Networking Reception, the Introduction to Medical Writing seminar, the Freelance Business Forum, lunches, refreshment breaks, and all conference materials.

Registration fees are payable in advance. Full payment is due by Monday 3 November 2014. EMWA reserves the right to refuse admission to the conference if payment has not been received and to request payment onsite at the late registration rate.

Workshop fees

Foundation	€150	£118
Advanced	€230	£182

Changes to registration: An administration fee of €25 will be charged for changes to registration (e.g. change of workshop choice or cancellation of a workshop). There is no fee for adding workshops or social events to your registration.

Cancellation of attendance: A refund, less an administration fee of €100, will be made for written cancellations of attendance received before midnight on Friday 3 October 2014. No refunds will be made after this date and FULL payment is due. Delegates are advised to ensure that they have adequate travel insurance cover in case they are obliged to cancel after midnight on 3 October 2014.

Payment methods: The preferred payment method is online by credit or debit card at the time of registration. If this is not possible, an invoice can be requested and payment made by bank transfer.

Registered accompanying guests: Accompanying guests who would like to attend the Opening Event and Networking Reception and 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 €165.

Registered accompanying carers: For accompanying carers the registration fee is reduced to €80 for the duration of the conference.

Social activities: Details and fees for social activities are provided in the social programme section of the brochure (page 14). EMWA members and registered and non-registered accompanying persons are welcome to attend social events on payment of the event fee.

Conference venue and accommodation

Grand Hotel Mediterraneo
Lungarno del Tempio, 44
50121 Firenze
Italy
Tel +39 055 660 241
www.hotelmediterraneo.com

Accommodation – conference venue

EMWA has reserved a number of rooms at the Grand Hotel Mediterraneo at the special rate of €125.00 per single occupancy room including VAT, breakfast, and complimentary WiFi. City tax will be charged at €4.00 per person per night and must be paid directly by the clients at checkout.

A link to a dedicated EMWA booking form for the Grand Hotel Mediterraneo is available below and on the Conference pages of the website. **Delegate Accommodation Booking Form**

The conference rate will be available until 10 October, after which the hotel reserves the right to offer rooms subject to availability at the prevailing rate.

Parking

Parking is available at the conference hotel in a private garage with surveillance (1 day €20 – 2 days €18 per day – from 3 days €15 per day). Please contact the hotel directly to arrange parking.

Accommodation – alternative hotel

EMWA has negotiated rates at an alternative hotel a short walk from the conference hotel. Please note that EMWA does not offer a recommendation for the accommodation quality or customer service for this hotel, but has negotiated rates of €80.00 per single occupancy night for the duration of the conference including VAT, breakfast, and complimentary Wi-Fi. City tax will also have to be paid by all guests on departure.

Please use the link to **download a booking form** and return it to the hotel by emailing fi.center@hotelbb.com or by fax +39 055 23 45 925.

The B&B Firenze City Centre
Viale Giovanni Amendola, 34
50121 Firenze
Tel +39 055 23 43 201
www.hotelbb.it

Travelling to the conference hotel

Arriving at Florence Airport

A shuttle service runs from Florence's Amerigo Vespucci International Airport to the Stazione Santa Maria Novella (train station), taking around 20 minutes and costing between €6 and €10. A taxi from the airport to the hotel will cost around €25 and take up to 20 minutes.

Arriving at Pisa Airport

Shuttle buses are operated by Terravision and RyanAir, running regular services to the Stazione Santa Maria Novella in Florence. The journey takes around an hour and costs between €10 and €12 return. To find the buses, leave the terminal building and turn right; immediately in front of you are kiosks for both bus services.

The conference hotel is a short taxi ride from the train station – about €10-€15, or you can catch the number 14 bus.

Conference overview

For full details of all workshops and leader profiles, please visit the

Online conference planner

Note: All workshops, except not-for-credit workshops and seminars, have pre-workshop assignments which must be downloaded directly from the online planner.

Thursday 6 November

11:00 onwards	**EMWA information desk opens** Collect your badge and conference documents
12:00–13:30	**Light lunch** Arno Restaurant
13:30–17:00 **DDF26**	**Introduction to Writing for Medical Devices** **(Drug Development — FOUNDATION)** Claudia Frumento (ICiMT International Communication in Medicine and Technology)
13:30–16:30 **MSF3**	**Basics of Epidemiology for Medical Communicators** **(Medical Science — FOUNDATION)** Rita Wellens (Wellens Clinical Research Consulting)
13:30–16:30 **MCF18**	**Abstracts** **(Medical Communication — FOUNDATION)** Phil Leventhal (4Clinics)
13:30–17:00 **DDA6**	**Advanced Clinical Study Design** **(Drug Development — ADVANCED)** Rosemary Bischoff (ClinWrite)
13:30–16:30 **PTF13**	**Critical Appraisal of Medical Literature** **(Professional Techniques — FOUNDATION)** Adam Jacobs (Freelance)
13:30–17:00 **DDF11a**	**Subject Narratives for Clinical Study Reports** **(Drug Development — FOUNDATION)** James Visanji (Trilogy Writing & Consulting GmbH)
13:30–17:00 **DDF12**	**The Clinical Study Protocol: Content and Structure** **(Drug development — FOUNDATION)** Walther Seiler (Bayer HealthCare AG)
15:15–15:45	**Refreshment break** American Bar
13:30–16:00	**Introduction to Medical Writing** **(Free 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. *(Continued)*

Conference overview (continued)

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.

17:30–18:50 **Opening Event**

President's Welcome, Julia Donnelly

Welcome to Tuscany, Andrea Rossi

What Scientific Societies Need from Medical Writers in the Mediterranean Region, Professor Ferdinando Fusco

Unlike traditional medical practice which relied upon the experience and superior intellect of the "great masters of medicine" to create "rules" based on their influential opinion, modern evidence-based medicine is founded upon the possibility of sharing medical knowledge, observations, empirical findings, and findings of clinical trials with the medical community worldwide, with a rapid exchange of information via print journals, books, and web-based publications. Medical and scientific research institutes and medical schools worldwide are still bound, in most cases, by old didactic concepts where a few leading authors - usually of (text) books - provide updated information to all of the medical community. If "medical reading" is intended for all physicians, this type of "medical writing" has so far only been for those who are involved mainly in academic pursuits.

Scientific societies which provide the forums where scientific and clinical research are presented and discussed are traditionally closer to the world of modern medical reading and medical writing. Medical writing is the most important form of communication for scientific societies dealing with medicine and comprises the written language used to disseminate, discuss, and exchange medical and scientific knowledge and ideas, formulate guidelines, and propagate medical education. The importance attached to medical writing by scientific societies is obvious from the number of courses dedicated to scientific reading and writing at scientific meetings.

Nowadays, basic competence in medical writing should be considered an integral part of medical training. Scientific societies are amongst the first to give due attention to the importance of medical writing, not only as a specialist activity in its own right, but as a necessary element in the CV of any medical doctor worldwide.

Meet the Executive Committee – as part of the opening session, each member of the Executive Committee will briefly introduce themselves.

19:00–21:30 **Networking Reception – The Tastes of Italy**

The welcome reception will introduce you to traditional Tuscan food and drink. An expert in food and wine pairing will demonstrate how the right combination can magically and dramatically change the way you taste the regional produce of Florence. A game where you will experience unique sensations that will inspire your medical writing … forever.

Conference overview (continued)

Friday 7 November

07:45 onwards	**EMWA information desk opens**
08:30–12:00 **DDF17a**	**Ethical Issues in Clinical Trials** **(Drug Development — FOUNDATION)** Art Gertel (MedSciCom, LLC)
08:45–12:15 **MCA4**	**Manuscript Writing: from Good to Excellent** **(Medical Communication — ADVANCED)** Kari Skinningsrud (Limwric as)
08:45–11:45 **DDF25**	**Orphan Drugs** **(Drug Development — FOUNDATION)** Christiane Breithaupt (Fresenius Medical Care Deutschland GmbH)
08:45–11:45 **PTF1**	**Data Presentation I: Tables and Graphs** **(Professional Techniques — FOUNDATION)** Barry Drees (Trilogy Writing & Consulting GmbH)
08:45–11:45 **MCF5**	**Overcoming Publication Hurdles: Dealing with Biomedical Journals** **(Medical Communication — FOUNDATION)** Elise Langdon-Neuner (Freelance editor and publications consultant in biomedical sciences)
08:45–12:15 **LWF2**	**Punctuation** **(Language and Writing — FOUNDATION)** Alistair Reeves (Ascribe Medical Writing and Translation)
08:45–12:15 **DDA5**	**The CTD Clinical Overview** **(Drug Development — ADVANCED)** Debbie Jordan (Freelance)
09:30–17.30	**EMWA Executive Committee Meeting**
10:00–10:30	**Refreshment break** American Bar
11:45–13:30	**Lunch** Arno Restaurant
12:30–13:15	**EMWA Budapest Working Group: ICH E3 and E6 Forensics – a 2-year roadmap for alignment with current practices** (Progress Update – Not for Credit) Sam Hamilton (EMWA Vice President and Budapest Working Group Chair) Art Gertel (EMWA Fellow and Budapest Working Group member)

EMWA is initiating a collaboration with many stakeholders, including professional associations, regulators, and key industry participants, to review the ICH E3 and ICH E6 guidelines in a 2-year project that began in May 2014. The EMWA-incepted Budapest Working Group (BWG) comprises experts in E3, E6 and protocol and clinical study report templates. We have strategists working with partner and stakeholder organisations including AMWA and EMA. Discussions are ongoing with other key parties. With stakeholder involvement from the outset, the aim of this project is to encourage the participation of all affected parties, to best ensure that the anticipated recommendations address the needs of the broadest possible community, following developments over the 20 years since these guidelines were first issued. Sam Hamilton (EMWA Vice President and BWG Chair) and Art Gertel (EMWA Fellow and BWG member) will present their first publication of the project.

Conference overview (continued)

13:30–16:30
DDF20

GCP Training for Medical Writers
(Drug Development — FOUNDATION)
Gillian Pritchard (Sylexis Limited)

13:30–17:00
DDA9

Medical Writing and Observational Studies
(Drug Development — ADVANCED)
Thomas Wagner (Trilogy Writing & Consulting GmbH)

13:30–17:00
DDF30

Writing Risk Management Plans
(Drug Development — FOUNDATION)
Tiziana von Bruchhausen (Boehringer Ingelheim GmbH & Co. KG)

13:30–16:30
MSF1

Pharmacology for Medical Writers: the Basics
(Medical Science — FOUNDATION)
John Carpenter (Freelance)

13:30–17:00
DDA1

Writing Global Submission Dossiers using the Common Technical Document
(Drug Development — ADVANCED)
Stephen de Looze (Freelance)

13:30–17:00
MSF7

Fundamentals of Immunology
(Medical Science — FOUNDATION)
Uma Swaminathan (GlaxoSmithKline Biologicals, Belgium)

13:30–17:00
DDF28

Paediatric Clinical Trials
(Drug Development — FOUNDATION)
Klaus Rose (klausrose Consulting)

15:15–15:45

Refreshment break
American Bar

17:15–18:45

Freelance Business Forum
(Discussion Forum – Not for Credit)
Kathryn White (Cathean Limited)
Alistair Reeves (Ascribe Medical Writing and Translation)

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. Light refreshments will be available before and during the Forum.

19:00

Social activities, see page 14

Conference overview (continued)

Saturday 8 November

07:45	**EMWA information desk opens**
08:45–12:15 **DDF18**	**Good SOP Practice: Processes and Authoring (Drug Development — FOUNDATION)** Tracy Farrow (PPD) Sam Hamilton (Sam Hamilton Medical Writing Services Ltd)
08:45–11:45 **MCF2**	**Developing a Communication Strategy for your Brand (Medical Communication — FOUNDATION)** David Collison (AXON Communications) Shanida Nataraja (AXON Communications)
08:45–12:15 **MCF17**	**Using Writing Guidelines for Manuscripts (Medical Communication — FOUNDATION)** Andrea Rossi (Eli Lilly Italy)
08:45–12:15 **LWA4**	**Beyond Simple Editing (Language and Writing — ADVANCED)** Barbara Grossman (Hawkeye Medical Limited) Marian Hodges (National Institute for Health and Care Excellence)
08:45–12:15 **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)
08:45–12:15 **PTA9**	**Analysis of Variance and Regression Analysis (Professional Techniques — ADVANCED)** Adam Jacobs (Freelance)
08:45–11:45 **MCF13**	**Management of Translation Projects (Medical Communication — FOUNDATION)** Laurence Auffret (CINETIQUE Translations)
10:00–10:30	**Refreshment break** American Bar
12:00–13:30	**Lunch and departure**

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Social programme

Friday 7 November

All activities depart from the lobby of the Grand Hotel Mediterraneo at 19:00 prompt

Florence by night walking tour

Maximum per tour – 20 people
Price: €18.00
Duration: 1.5 hours

A guided walk through the streets of Florence, taking in the architecture and famous sights, starting with Lungarni boulevards and on to the Santa Croce Square, Palazzo Vecchio, passing the Uffizi Gallery, the Ponte Vecchio, the Cathedral and the Palazzo Pitti.

Private organic wine tasting

Maximum per tour – 15 people
Price: €42.00
Duration: 2 hours (including taxi transfers)

In 2010, two young organic winemakers opened a wine bar in the heart of Florence. A private wine tasting will be held on their premises. During the wine tasting, you can speak directly with the sommelier, who will explain the history and technical information behind the wines.

The tasting will be accompanied by some local delicacies such as Tuscan charcuterie, tasty cheeses from small local farms, and homemade biscuits and sweet wine.

Social programme (continued)

Ice cream and sweet treats walking tour

Maximum per tour – 25 people
Price: €32.00
Duration: 2.5 hours

A walking tour in the Old Town of Florence to some of the most important sights of the city: Piazza della Signoria and, of course, the Ponte Vecchio. An amazing walk through narrow, medieval streets typical of Florence. The walk takes in two fabulous stops to satisfy anyone's sweet tooth: First, the famous Vivoli Gelateria where – despite the time of year – you can sample some of the best ice cream Italy has to offer; and second, the Finisterrae Restaurant and Gelateria where you can taste other typical Italian sweets (babà, cannaoli, little fruit cakes) and maybe the owners will share some of their production secrets!

Florentine food and wine walk

Maximum per tour – 25 people
Price: €36.00
Duration: 2.5 hours

A tour to discover the tastes and flavours of Tuscany: oil and wine, cheese and bread. Genuine, selected products made by traditional methods. We will walk through the narrow, ancient streets of the centre of Florence speaking about our food tradition, and along the way making two separate stops to try delights such as crostini (toasted bread with sauces), schiacciata (oil bread), bistecca alla fiorentina, different kinds of cheese and bruschettas, mozzarella, prosciutto, salame, spaghetti, tortelli, lampredotto and different kinds of Chianti and Tuscan wines.

Speaker profiles

Ferdinando Fusco MD, PhD
University Federico II of Naples

Ferdinando Fusco is an Assistant Professor of Urology at the University Federico II of Naples. He is actively involved as a board member or section chairman in a number of scientific societies, including the Italian Society of Urology, Italian Society of Andrology, European Section of Andrological Urology, and European Society of Sexual Medicine. He serves as a reviewer for numerous peer-reviewed scientific journals, and until 2014 he was Editor of the PubMed indexed journal Archivio Italiano di Urologia ed Andrologia. He has been the author of about 80 manuscripts, several short communications, abstracts, and book chapters on urology, andrology and sexual medicine.

Helen Baldwin PhD
Scinopsis

Helen is a pharmacologist with over 25 years of experience in the biomedical field. As a research scientist in academia and the pharmaceutical industry, she authored 30 publications in scientific journals. She then spent 5 years as project leader of European clinical trials in a CRO. In 1999 she started working as a freelance medical writer in the South of France. Then in 2006 she set up Scinopsis, a service company with a small team of medical writers. Her expertise includes writing of CSRs, protocols, CTD clinical summaries and overviews, manuscripts, and biomedical translations. Helen served on the EPDC from 2006 to 2007 and held the posts of EMWA Vice President from 2007 to 2009 and President from May 2009 to May 2010.

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. In addition to the EMWA Freelance Business Forum, Kathryn is an active member of a UK freelance clinical research forum, and alongside her 'day job' as a medical writer, she is an equestrian journalist.

Workshop leader profiles

Laurence Auffret MSc Bioeng, MA Ling, MCIL
CINETIQUE Translations

Laurence founded CINETIQUE Translations (ISO 9001:2008) in 2003 after working as a scientist in France and a language lecturer in UK universities (Translation, Computer-assisted learning, Erasmus International programmes). CINETIQUE Translations specialises in language services (translation, interpreting and writing) for science, technology and engineering with a strong focus on clinical trials documentation. Laurence and her team currently manage large translation projects for European and US-based clients. In May 2009, Laurence also became part of EMWA's EC and was President of EMWA from May 2010 to May 2011.

Workshop leader profiles (continued)

Susan Bhatti PhD
Merck Serono

Susan has spent over 15 years working in regulatory affairs in both the pharmaceutical industry and the CRO industry. She can therefore share many years of experience of interacting with European regulatory authorities and is an expert in European regulatory requirements. She has been responsible for the submission of clinical trial applications and marketing authorisation applications in many countries in Europe as well as participating in scientific advice meetings with the EMA and national regulatory authorities. Over the years she has had firsthand experience of the increasing complexity of the regulatory environment that has accompanied the growth of the European Union. Susan was elected as Vice President of EMWA in May 2011 and served as President from May 2012- to May 2013.

Rosemary Bischoff MS
ClinWrite

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

Christiane Breithaupt DVM
Fresenius Medical Care Deutschland GmbH

Christiane began her career as a veterinary surgeon before joining the CRO industry as a medical writer. In this role she was responsible for writing, reviewing and editing study protocols and study reports and other study related documents. From medical writing, Christiane moved into the area of regulatory affairs. Here, she gained extensive experience in clinical trial submissions; submission and maintenance of marketing authorisation applications; conduct of scientific advice discussions with European regulatory authorities; and preparation, submission and maintenance of orphan drug designations and Paediatric Investigation Plans. She is currently working as a regulatory affairs manager at Fresenius Medical Care, Germany.

John Carpenter BSc, PhD
Freelance

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 Infrared 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.

Workshop leader profiles (continued)

David Collison BSc, PhD
AXON Communications

David began his career as a medical writer over 8 years ago, following his PhD in cell biology and two postdoctoral research positions in an ophthalmology-related discipline. During this time, David has gained experience in developing and delivering a range of healthcare communications materials, encompassing strategic publication planning, primary and review publications, congress activities, medical education tools and campaigns, and symposia and advisory boards, for a range of innovative pharmacotherapies and devices, spanning all phases of development from preclinical, through clinical to launch. As a Senior Medical Writer at AXON, David is responsible for disseminating complex medical and scientific information in a digestible form for a range of target audiences, including specialists, general practitioners, nurses and patients. He has worked in numerous therapeutic areas, including ophthalmology, oncology, diabetes, chronic kidney disease and gastroenterology. David has been a member of EMWA since 2011 and became a workshop leader in 2013.

Stephen de Looze MA (Oxon), PhD, Editor in the Life Sciences
Freelance

After a 10-year research career (publishing in fields as diverse as plant biorhythms and mouse genetics), Stephen established Medical Writing with Hoechst Frankfurt (now Sanofi) in 1985, built the department and developed writing standards for clinical research documents. He was then Director of Medical Writing and Electronic Publishing at Accovion GmbH 2002-2013 before becoming a freelance consultant in medical writing. He served on international ICH committees for clinical study reports (ICH E3) and the Common Technical Document (ICH M4), and has been active as a member, teacher and lecturer in EMWA (founder member), AMWA, EASE, DIA, Management Forum and other organisations. He served on the EMWA Professional Development Committee (EPDC) from 2000 to 2011 including three terms as Education Officer 2001–2003, 2007–2009 and 2009–2011. He was elected a Fellow of EMWA in 2009.

Barry Drees PhD, Editor in the Life Sciences
Trilogy Writing & Consulting GmbH

Barry Drees was a witness to the start of the genetech madness when he got his PhD in molecular genetics at the University of California at San Francisco at the time of the founding of Genentech. Life's sense of irony took him to Germany, however, where he worked as a medical writer in the pharmaceutical industry for 12 years, setting up a Phase I writing group and leading several regulatory submission teams, among other activities. Barry is a frequent speaker on medical writing, statistics and other scientific communication topics for Management Forum Ltd, as well as various pharmaceutical associations. He also speaks on non-scientific topics such as the introductory presentation on the history of Malta at the 20th EMWA conference. He has appeared on an educational television programme in Germany to discuss the ethics of genetic engineering and German radio to discuss medical writing as a career. He is the former Editor-in-chief of 'The Write Stuff', the Journal of EMWA (now called 'Medical Writing'), and is currently a Senior Partner at Trilogy Writing & Consulting. He served on the EMWA Professional Development Committee (EPDC) 2006–2009, with a focus on Train-the-Trainer events. Barry is a Nick Thompson Fellow of EMWA.

Tracy Farrow GIBiol
PPD

Tracy Farrow, 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 managing multiple clinical study reports, and Quality Manager for Data Management where she was responsible for internal and external 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) G.I.Biol in Biochemistry in 1993 after gaining two Higher National Certificates in haematology and chemistry.

Workshop leader profiles (continued)

Claudia Frumento PhD
ICiMT International Communication in Medicine and Technology

Claudia has a PhD in medical information technology. She graduated from the University of Buenos Aires and received a German scholarship to do her PhD thesis in the University of Heidelberg. She has more than 16 years experience in the field of medical technology acquired as Product Manager and European Training and Education Manager for international medical technology corporations, Guidant and Medtronic, and has been a lecturer at the University for Applied Sciences Giessen–Friedberg (International B2B Marketing and Business English for Mechanical and Industrial Engineers). She speaks three languages fluently (English, German and Spanish) and has vast experience in international project management such as: product launches, pan-European training and programmes for physicians, multicentre clinical trials and writing for the medical device and pharmaceutical industries. She is the coordinator of the ICiMT expert team. Claudia is a member of the EMWA Professional Development Committee.

Art Gertel PhD
MedSciCom, LLC

Art has a background in neurophysiology and behavioural medicine. He has recently become an independent consultant, specialising in strategic regulatory, Data Safety Monitoring Board management, medical writing, and bioethics. Art is also a Senior Research Fellow with the Centre for Innovation in Regulatory Science (CIRS) – a London-based think-tank, focused on improving the decision-making process in medicines development, review, and approval. Art has held senior posts at a number of other companies including Schering-Plough, Hoffmann-LaRoche, TFS, and Quintiles. He 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 on the 'cutting edge' in an eDC 'dot.com' company, and is active in CDISC. He serves as Co-Chair of the Global Ethics and Regulatory Initiative (GERI) of the Alliance for Clinical Research Excellence and Safety (ACRES). He is a Past President of AMWA and is a Fellow of both AMWA and EMWA.

Barbara Grossman BSc
Hawkeye Medical Limited

As well as a passion for proofreading and quality control, Barbara has more than 20 years' experience of medical writing and editing in the pharmaceutical industry. Before starting her own medical writing and consultancy business (Hawkeye Medical Limited), she built up and managed the medical writing group at Covance, the CRO, working in a wide range of therapeutic areas. Barbara has hands-on experience of preparing a variety of clinical documents, and has managed several large writing programmes. She has presented or run workshops at educational institutions and organisations such as BARQA, DIA (Europe and USA), Management Forum and NICE, and led many company-internal training courses. Barbara has been an EMWA workshop leader since 2001, and was a member of the ICR 'Study Start-up Expert Working Group'. She is a Fellow of EMWA, and currently serves on the Executive Committee as Education Officer.

Sam Hamilton PhD
Sam Hamilton Medical Writing Services Ltd

Sam is a postdoctoral virologist with a multidisciplinary clinical research background since 1994. She specialised in regulatory medical writing from 1998, and most recently managed the UK Medical Writing group for the 5th largest CRO globally before going freelance in 2006. Sam co-founded the freelance feature section 'Out On Our Own' in 'Medical Writing', EMWA's journal; is on the journal's Editorial Board; co-authored the 2007 and 2012 EMWA Freelance Business Survey publications; and advocated for the freelance contingent and hosted the Freelance Business Forum at EMWA conferences over a 7-year period to 2014. Sam has been a workshop leader since 2008, and has developed content for EMWA spring conferences from 2008 to 2013. Sam is currently EMWA Vice President.

Workshop leader profiles (continued)

Marian Hodges BSc
National Institute for Health and Care Excellence

Marian has more than 20 years' experience of medical writing and editing. Currently, she is Associate Director (Publishing) in the Communications team at the National Institute for Health and Care Excellence (NICE). At NICE, she is responsible for a team who edit and publish documents from all of the NICE work programmes. Before joining NICE, Marian was a freelance medical writer and editor, working on a wide range of materials for pharmaceutical, medical communication and publishing companies. She has been an EMWA workshop leader since 2001, and has also run workshops for other organisations, as well as training for colleagues at NICE. Marian is a Fellow of EMWA and currently serves on the EMWA Professional Development Committee (EPDC).

Adam Jacobs PhD, MSc, FICR, CSci Dip, IoD, Dip Econ
Freelance

After getting bored with 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 (www.dianthus.co.uk) in 1999, and has subsequently taken a part-time MSc course in medical statistics, which he completed in 2002. Adam was EMWA president in 2004–2005, was co-author of EMWA's guidelines on the role of professional medical writers in publications, and currently holds the role of EMWA's press officer. He is still not bored with medical writing.

Debbie Jordan BSc (Hons), MIBiol, CBiol, Dip Clin Sci
Freelance

Debbie has been working in the pharmaceutical industry for over 20 years in both pharmaceutical company and CRO environments. She has worked as a data assistant, CRA and project manager, before moving into medical writing. Fifteen 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 served on the Executive Committee of EMWA for 2 years between 1997 and 1999.

Elise Langdon-Neuner BSc, Editor in Biomedical Sciences
Freelance editor and publications consultant in biomedical sciences

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

Workshop leader profiles (continued)

Phil Leventhal PhD
4Clinics

Phil is currently a Scientific Writer at 4Clinics in Paris, France 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, Phil is currently Editor-in-Chief of EMWA's official journal, 'Medical Writing'.

Shanida Nataraja BSc, PhD
AXON Communications

Shanida became a medical writer more than 13 years ago, after completing a PhD and a 2-year postdoctoral research fellowship focusing on the neurophysiology of learning and memory. During this time, Shanida has had the opportunity to work on a wide range of different medical communications, marketing, public relations and clinical trial communications support activities in numerous therapeutic areas, including cardiology, oncology, psychiatry and diabetes. Currently, Shanida is Director of Editorial & Scientific Excellence at AXON Communications, a global healthcare consultancy firm, where she is responsible for, amongst other things, providing high science, strategic and editorial input into new and existing accounts, as well as leading the training and editorial committees. Shanida has been involved in both preparing for and implementing numerous strategic workshops for key pharmaceutical brands, and has developed market and competitor landscape reviews, strategic communication plans, strategic publication plans and marketing plans for these key brands. Shanida has been a member of EMWA since 2001, and between 2006 and 2012, Shanida became EMWA's website manager, working with a team of people to develop EMWA's website and other online technologies. As such, she was a member of EMWA's Executive Committee for 6 years, and she is also an experienced workshop leader, having run a workshop for medical communicators for several years.

Gillian Pritchard MSc, MRCP, MFPM, MBA
Sylexis Limited

Gillian is a pharmaceutical physician and medical writer with many years experience of designing, conducting and reporting clinical trials, from the perspective of an investigator in academia, as a research physician in phase I and II clinical trials and as a clinical project manager of phase III trials with a global pharmaceutical company. Gillian also has experience working with a pharmaceutical and medical devices consultancy where she developed and delivered GCP and safety monitoring training courses for investigators. In 2006 she established Sylexis Ltd. which provides regulatory writing services for pharmaceutical and medical device clients. Gillian was EMWA Treasurer from 2009 to 2013.

Alistair Reeves BA (Hons), Editor in the Life Sciences
Ascribe Medical Writing and Translation

Alistair became a freelance writer, editor and trainer in 2002 after 25 years in the pharmaceutical industry in different roles in market research, clinical research, drug regulatory affairs, medical translation, medical writing, case report form design, and document management and publishing. He has extensive writing and editing experience in a wide range of clinical areas including endocrinology, oncology, infectious diseases, cardiovascular medicine, transplant surgery, traumatology and veterinary and laboratory medicine. Over the past 25 years, he has presented courses on many aspects of medical writing for commercial training organizations and regularly holds in-house courses for small and large pharmaceutical companies throughout Europe. He has given more than 50 workshops at almost all EMWA events since 1997 and is an Honorary Fellow of EMWA. He has also been a major contributor to 'The Write Stuff' and 'Medical Writing' with articles on language issues. Alistair served as EMWA Conference Director from 2012 to 2014, and has recently returned to the role of EMWA Freelance Advocate while Sam Hamilton concentrates on other commitments as Vice President.

Workshop leader profiles (continued)

Klaus Rose
klausrose Consulting

Klaus is CEO of klausrose Consulting, Switzerland, supporting pharmaceutical companies in paediatric drug development to comply with FDA and EMA requirements. He qualified in 1986 in medicine after studying romance languages and psychology. He completed his postgraduate clinical training in general medicine and joined the pharmaceutical industry in 1991. He held various positions in R&D and medical affairs, finally becoming Global Head Paediatrics at Novartis between 2001 and 2005, and then Global Head Paediatrics at Roche until 2009. He worked with a regulatory consultancy before establishing his own business. He is a frequent speaker at international conferences on paediatric drug development and publishes on a regular basis. The second edition of 'Guide to Paediatric Drug Development and Clinical Research', co-edited with Professor John van den Anker, was released in May 2010. His private interests include Mediterranean cooking, wine, gardening, romance languages, and the classical guitar.

Andrea Rossi
Eli Lilly Italy

Andrea Rossi has a degree in biology from Florence University. After a brief spell at the University, he started working for 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 medical writer since 2003. He is author of more than 400 disclosures and acknowledged for his contribution in several others. From 2007 to 2009 he was on the coordination board of BIAS (Biometristi Italiani Associati) and has been an EMWA member since 2004. Andrea has acted as a trainer for statistics and medical writing in a number of Italian postgraduate medical schools, and has been a speaker at national and international conferences. Andrea served as EMWA President from 2013 to 2014.

Walther Seiler PhD, Editor in the Life Sciences
Bayer HealthCare AG

After a classic education as a zoologist, Walther received his PhD in neuroendocrinology. Throughout his academic career, he enjoyed interpreting and presenting data at least as much as generating them. Thus, stepping into medical writing thereafter was only a logical consequence. After more than 8 years of medical writing at an international CRO, Walther moved to a global pharma company where his overall medical writing experience has now accumulated to more than 20 years. He has witnessed EMWA's development since its early infancy.

Kari Skinningsrud MS (Chem)
Limwric as

Kari has been a freelance medical writer in Norway since 2002, and has worked in the pharma industry for more than 10 years. She has experience with regulatory writing, but has moved more into medical communication and training during the last years. She has given courses about manuscript writing to PhD candidates at the Medical Faculty, University of Oslo (in Oslo and at their representative office in St. Petersburg), the Norwegian University of Science and Technology (Trondheim), the University of Zimbabwe and at the KCMC in Tanzania. She gives EMWA workshops about manuscript writing, grant-writing and cross-cultural communication and is currently serving on EMWA's Professional Development Committee.

Workshop leader profiles (continued)

Uma Swaminathan MSc, MBA
GlaxoSmithKline Vaccines, Belgium

Uma's passion for medical writing brought her all the way from Bangalore (India) to Belgium. During her scientific writing career of over 7 years at GSK, Uma has worked on a wide range of regulatory and disclosure documents across different vaccine projects. Her current role as Manager for Clinical Trial Register and Protocol Posting within GSK has allowed her to further develop her skills in the field of project management and scientific communication. These include such diverse activities as understanding and complying with the complex and ever-changing legal and regulatory requirements for disclosure; planning, tracking and delivery of protocol and results summaries; cross-functional training; and increasing the public disclosure awareness within the company.

James Visanji PhD, MCIL
Trilogy Writing & Consulting GmbH

Following a PhD in medical sciences at Manchester University, postdoctoral work in oncology in Italy, and a brief stint as a freelance translator, James became a medical writer in 2006. Formerly deputy director of medical writing at Accovion, James is now a medical writing manager at Trilogy Writing and Consulting in Frankfurt. His focus is on clinical and regulatory documentation, in particular study protocols, reports and CTD clinical summaries and overviews. James has been a member of EMWA since 2007. James was elected as Treasurer of EMWA in May 2013.

Tiziana von Bruchhausen PhD
Boehringer Ingelheim GmbH & Co. KG

After spending 8 years in basic research on neurosecretion, diabetes, and stem cell differentiation, Tiziana decided to leave her beloved confocal microscope and to follow her passion for writing and presenting data. She held a position as a medical writer at a CRO, where by chance she stepped into the pharmacovigilance world and fell in love with it. She specialised over 4 years in drug safety and put together her two passions, becoming a safety writer. Tiziana gained first-hand experience with the 'Pharma Package' and its challenges when writing safety documents. After working for nearly 2 years as a freelance safety writer and consultant, she is currently working as a senior safety writer at Boehringer Ingelheim.

Thomas Wagner PhD
Trilogy Writing & Consulting GmbH

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 back in 2009 to the other side of the fence as a service provider and consultant now working for Trilogy Writing & Consulting as a Medical Writing Manager.

Rita Wellens MSc, PhD
Wellens Clinical Research Consulting

Rita has 20-years-plus experience with project management (Phase I-IV), training, and medical writing for pharmaceutical companies and CROs. She managed epidemiology projects worldwide for GlaxoSmithKline Biologicals and specialised in pharmacoepidemiology and pharmacosurveillance at the London School of Hygiene and Tropical Medicine. She held university faculty positions mainly in the USA that included teaching epidemiology, biostatistics, and research methodology. She received several NIH and AHA grants to pursue her academic research and authored numerous publications. Rita strongly feels that medical writers have a key role in the critical appraisal and sound reporting of medical findings. She served on the EMWA Professional Development Committee (EPDC) from 2007 to 2010, was elected EMWA Vice President in May 2010 and continued as President from May 2011 to May 2012.

EMWA Executive Committee

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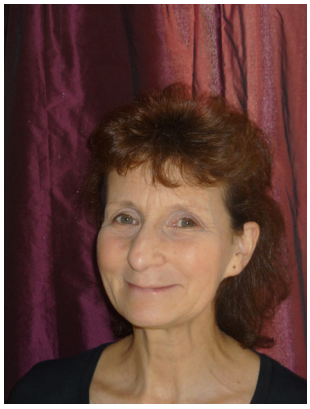

Barbara Grossman
Education Officer

FUTURE EVENTS

40th EMWA Conference

5–9 May 2015

The Hilton DoubleTree Hotel, Dublin, Ireland

41st EMWA Conference

5–7 November 2015

The Bel Air Hotel, The Hague, Netherlands

42nd EMWA Conference

10–14 May 2016

The Sheraton Hotel, Arabella Park,
Munich, Germany

43rd EMWA Conference

3–5 November 2016

Sheraton Brussels Hotel
Brussels, Belgium

40th EMWA Conference

EUROPEAN
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The Hilton DoubleTree Hotel, Dublin, Ireland

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