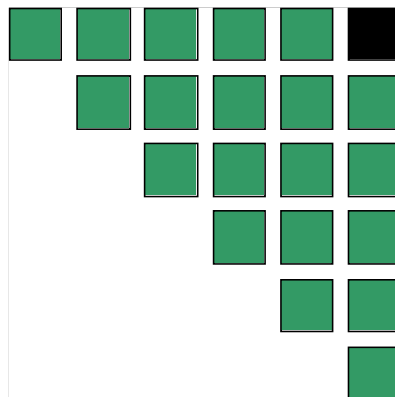


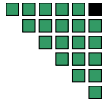
European  
Medical Writers  
Association

**EMWA**  
**Professional**  
**Development Programme**

**Brochure**  
**October 2009**



## **The EMWA Professional Development Committee**



Stephen de Looze, Education Officer (Chairman)

John Carpenter

Julia Donnelly

Barry Drees

Douglas Fiebig

Sofija Micic

Rita Wellens

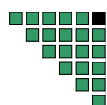
Jo Whelan

Email: [epdc@emwa.org](mailto:epdc@emwa.org)

*This brochure was prepared by Stephen de Looze on behalf of the EMWA Professional Development Committee, which issued this edition in October 2009*

---

## **Table of Contents**



1. Introduction .....	4
Foundation & Advanced Levels .....	4
Accreditation.....	5
Conferences .....	6
Non-Credit Workshops and Seminars .....	7
2. Available Workshops .....	8
3. Workshop Abstracts & Workshop Leaders.....	13
4. Enrolment & Fees .....	14
Enrolling in the EPDP .....	14
Fees .....	15

## 1. **Introduction**

*The EMWA Professional Development Programme* (EPDP) provides high-quality training for medical writers through workshops and homework assignments. Workshops are selected, developed and approved for inclusion in the EPDP by the EMWA Professional Development Committee (EPDC), under the chairmanship of the EMWA Education Officer. The approval process is described in the Workshop Leaders Handbook, available on the EMWA website, [www.emwa.org](http://www.emwa.org).

By completing eight different workshops, participants can obtain an EPDP certificate, as described below. This is one of the few opportunities of obtaining a qualification in medical writing.

One important aim of the EPDC is to ensure that EMWA certification is regarded by the medical writing community, employers and clients as a valuable qualification. To achieve this, the EPDC strives to ensure a high level of quality for workshops and workshop leaders, and to ensure that participants meet the required standards of performance to obtain credit when completing workshop requirements.

### ***Foundation & Advanced Levels***

---

There are two levels of certificate: *foundation* and *advanced*.

An EPDP **specialised** or **multidisciplinary** certificate at foundation level is awarded to candidates who have gained credits for eight different foundation workshops as follows:

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

Candidates may obtain more than one specialised foundation certificate after completing the appropriate requirements for each certificate.

An EPDP certificate at advanced level is awarded to candidates who obtain credit in any eight different advanced workshops. Advanced certificates are limited to one per candidate.

### **Accreditation**

Candidates for EPDP accreditation must be EMWA members and must also be enrolled in the EPDP (see section 4) in order to be eligible for credit.

It is possible to participate in a workshop without being enrolled in the EPDP, but no credit towards an EMWA certificate will be awarded for that workshop, even if the participant enrolls in the EPDP later; credit cannot be awarded retrospectively.

It is possible to be enrolled either at the foundation level, or at the advanced level, or at both levels simultaneously. There are no formal prerequisites (e.g. completion of a foundation level certificate) to enrol at advanced level. However, to obtain maximum benefit from the workshop and minimise the risk of failing a workshop, candidates are strongly advised to select each workshop according to their educational needs and experience in that particular area.

To receive credit for an approved workshop, candidates must successfully:

- Complete a pre-workshop assignment and a needs analysis questionnaire (usually up to 2 hours)
- Attend the workshop itself (3 or 3.5 hours)
- Complete a post-workshop assignment (usually up to 3 hours)

The times required to complete the pre-workshop and post-workshop assignments are a general guide only, and individual participants may require more or less time depending on their experience.

Candidates must submit assignments to the workshop leader by the deadlines provided by the workshop leader to qualify for credit.

## **Conferences**

---

EMWA holds a spring and an autumn conference in different European cities each year. These are the only events where EPDP workshops are available for credit. Many additional activities outside the educational programme will be available to conference attendees; full details are provided in each conference brochure.

The Education Officer assembles the workshop programme at each conference, ensuring a balance of workshop options and levels at each session. Popular workshops that are frequently oversubscribed may be run more than once. The workshops offered at each conference depend on several factors such as the availability of the workshop leaders and the size of the conference. Normally, several workshops are run in parallel during each conference session.

Attendance per workshop is limited to 32 participants for foundation workshops and 20 participants for advanced workshops (some workshops have a lower limit to suit their educational objectives).

Candidates may register for **up to four** credit workshops at any one conference. Workshop places are allocated on a first-come-first-served basis.

---

### ***Non-Credit Workshops and Seminars***

---

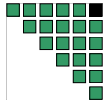
Workshops that are not EPDP-approved may also be available at the EMWA conferences. These workshops will not count towards the EPDP certificate.

Some of these workshops may be in the final stage of approval for subsequent inclusion in the EPDP and are offered at a discounted rate (see section 4). Such workshops are described in the conference brochures as “under assessment”. Although the standard of these workshops is expected to meet the EPDP standard, participants will receive no credit towards an EPDP certificate from attending these workshops. Even if the workshop is subsequently approved and included in the EPDP, retrospective credit **cannot be awarded** for participation while under assessment.

As a complement to the educational programme, EMWA conferences also offer short workshops (1.5 hours), “soft skills” and other special interest workshops that are not for credit, as well as events such as seminars and discussion forums that are not part of the EPDP.

There is no restriction on the number of non-credit workshops or other events that may be attended at any one conference.

## 2. **Available Workshops**



Currently approved workshops and those currently under assessment are listed below together with their codes (DDF1, DDF2, etc.)<sup>1</sup>. In some cases, the same or similar topics are covered from different perspectives by different workshop leaders. Participants should read the workshop abstract (see section 3) if they are not sure which choice to make between similar workshops.

### **Drug Development, foundation**

Writing Clinical Study Reports using ICH E3	DDF1	Stephen de Looze
The Investigator's Brochure	DDF2	Barry Drees
Writing the Clinical Study Protocol	DDF3	Virginia Watson
The Patient Information Leaflet	DDF4	Wendy Kingdom
From Protocol to Study Report: What's In-between?	DDF6b	Franziska Pirkl
Introduction to Pharmacokinetics	DDF7	John Carpenter
Introduction to Quality of Life	DDF8	Beate Wieseler
European Regulatory Procedures for Medical Writers	DDF10c	Viola Hoffmann
Subject Narratives for Clinical Study Reports	DDF11	Gail Gerhartz
The Clinical Study Protocol: Content and Structure	DDF12	Walther Seiler
Basic Concepts of Study Design in Clinical Development	DDF13	Rosie Bischoff and Adam Jacobs
Ethical Issues in Clinical Trials	DDF17	Art Gertel and Farhad Handjani
Good SOP Practice: Processes and Authoring	DDF18	Sam Hamilton and Tracy Farrow
The EU Clinical Trials Directive	DDF19	Susan Bhatti
GCP Training for Medical Writers	DDF20	Gillian Pritchard
Quality Awareness in Clinical Study Report Development (under assessment)	DDF21	Nicky Dodsworth

<sup>1</sup> Workshop codes also appear in the conference brochures and web pages. Occasionally, a workshop leader may make adjustments to the workshop title: if the content of the workshop remains the same, the workshop retains the same code. A lower case letter is added to the code when there is a change of workshop leader or co-leader but the content remains the same.

## Drug Development, foundation (continued)

Drug Safety for Medical Writers Part 1: Adverse Events and Concomitant Medications	DDF22	Wendy Kingdom and Gillian Pritchard
Drug Safety for Medical Writers Part 2: Laboratory Data	DDF23	Wendy Kingdom and Gillian Pritchard

## Drug Development, advanced

Writing Global Submission Dossiers using the Common Technical Document	DDA1	Stephen de Looze
Medical Writing Between Dossier Submission and Drug Approval	DDA2	Douglas Fiebig and Neil Garrett
The CTD Clinical Summary	DDA3	Debbie Jordan
e-Submissions	DDA4	Art Gertel
The CTD Clinical Overview	DDA5	Debbie Jordan
Advanced Clinical Study Design	DDA6	Rosie Bischoff
Serving Two Masters: Comparing and Contrasting US and EU Regulatory Submissions and Processes	DDA7	Art Gertel and Susan Bhatti
Medical Writing and Observational Studies	DDA9	Thomas Wagner
Introduction to the Paediatric Investigation Plan Application	DDA10	Douglas Fiebig and Wolfgang Thielen
Audits and Inspections: What medical writers should know about audits and inspections and how to meet the expectations of auditors and inspectors	DDA11	Volker Peinke
Periodic Safety Update Reports	DDA14	Alison Rapley
Developmental Safety Update Reports (under assessment)	DDA15	Julia Cooper

## Language and Writing, foundation

Punctuation	LWF2	Alistair Reeves
Medical and Pharmaceutical English for Non-Native Speakers	LWF4	Susanne Geercken and Alistair Reeves
Syntax, Meaning and Word Order	LWF6	Alistair Reeves
Sharpen Up Your Writing Skills	LWF8	Jo Whelan
Summarising	LWF9	Wendy Kingdom
Essentials of Editing and Proofreading Part 1	LWF13	Barbara Grossman and Marian Hodges
Essentials of Editing and Proofreading Part 2	LWF14	Barbara Grossman and Marian Hodges

## Language and Writing, advanced

Collocations in Medical Writing and Translation	LWA3	Sofija Micic
Beyond Simple Editing	LWA4	Barbara Grossman and Marian Hodges
Master Class: Editing and Rewriting English Texts Originating from Non-Native Speakers	LWA5	Rosie Bischoff and Alistair Reeves
Master Class: Semantic Analysis of Medical Writing	LWA7	Michael Schneir
Impact of Language and Culture on Medical Writing	LWA8	Susanne Geercken and Alistair Reeves
Master Class: Syntactic Analysis of Medical Writing: Adverbs	LWA9	Michael Schneir
Tense	LWA10	Susanne Geercken and Alistair Reeves
	LWA11	Susanne Geercken and Alistair Reeves

## Medical Communication, foundation

Writing Successful Manuscripts (under assessment)	MCF1	Julia Forjanic Klapproth and Phil Leventhal
Developing a communication strategy for your brand (under assessment)	MCF2	Shanida Nataraja
Creating an Impact with Posters	MCF3	Julia Donnelly
Communication in Multidisciplinary Teams	MCF4	Andrew Walker and Jonathan Edwards
Overcoming Publication Hurdles: Dealing with Biomedical Journals	MCF5	Elise Langdon-Neuner
Publication Planning	MCF6	Julia Donnelly
Targeting your Audience	MCF7c	Julia Forjanic Klapproth and Lisa Chamberlain James
From Clinical Study Report to Manuscript	MCF8	Helen Baldwin
Health Communication: How to Achieve Your Objectives	MCF10	Catherine Mary
Conference and Meeting Reporting	MCF11	Lisa Chamberlain James and Nicky French
Grant Writing: A Business Opportunity for Medical Writers? (under assessment)	MCF12	Kari Skinningsrud

## Medical Communication, advanced

Publication Strategy	MCA1	Julia Donnelly
Systematic Reviews	MCA3	Beate Wieseler

## Medical Science, foundation

Pharmacology for Medical Writers: Part 1 – The Basics	MSF1	John Carpenter
Pharmacology for Medical Writers: Part 2 – Drugs Acting on Peripheral Body Systems: Hormones, Inflammation, Gastrointestinal System	MSF2	John Carpenter
Basics of Epidemiology for Medical Communicators	MSF3	Rita Wellens
Pharmacogenetics	MSF4	Andrea Palluch
Medical Writing for Vaccines	MSF5	Lily Remacle and Christine Vanderlingen
Why do drugs and medicines have adverse effects? (under assessment)	MSF6	John Carpenter
Fundamentals of Immunology (under assessment)	MSF7	Lily Remacle and Uma Swaminathan

## Medical Science, advanced

Advanced Epidemiology	MSA1	Rita Wellens
Cancer Vaccines (under assessment)	MSA2	Sunethra Wimalasundera

## Professional Techniques, foundation

Data Presentation I: Tables and Graphs	PTF1	Barry Drees
Information Sources for Medical Writers	PTF2c	Alison Dev
Using Statistics in Medical Writing	PTF3	Barry Drees
Medical Writing and Quality Control: Clinical Study Reports	PTF4	Alison McIntosh
Medical Writing and Quality Control of Documents Entering the Public Domain: Manuscripts and Abstracts	PTF5	Alison McIntosh
Cross-Cultural Communication	PTF8	Kari Skinningsrud
Writing PowerPoint Slide Kits	PTF10	Richard Clark
Web Wizardry: How to Create a Website	PTF12	Shanida Nataraja
Critical Appraisal of Medical Literature	PTF13	Adam Jacobs
Time Management for Medical Writers	PTF14	Debbie Jordan
Interpreting and Reporting Measures of Risk	PTF15	Tom Lang
Vendor-client Relationships: Marriage or Mismatch?	PTF16	Adam Jacobs and David Edwards
Psychology of Reading (under assessment)	PTF17	Thomas Schindler
Writing for the Internet (under assessment)	PTF18	Jo Whelan

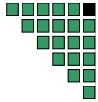
## **Professional Techniques, advanced**

Statistical Thinking for Medical Writers	PTA1	Victoria Cairns
Do More with Less Faster: Project Management for Biomedical Communications	PTA2	Art Gertel
Slippery slopes: Survival Analysis and Regression Clouds (Kaplan-Meier, Correlation and Regression Analyses)	PTA3	Barry Drees and Thomas Schindler
Data Presentation II: Advanced Data Presentation	PTA4	Barry Drees
Interpreting and Reporting Diagnostic Test Characteristics	PTA5	Tom Lang
Scheduling and Proposal Writing: The Clinical Study Protocol and Report	PTA6	Sam Hamilton
Document Review: Review Processes and Technical Aspects	PTA7	Volker Peinke
Statistical Analysis of Binary Data (under assessment)	PTA8	Adam Jacobs

## **Soft Skills**

Avoiding Back Pain at the PC: A Therapeutic Self-Help Session using the Alexander Technique	SSK1	Alice Knight
Mentor-guided Analytical Thinking (MAT): A Method for Training Medical Writers and Editors	SSK2	Tom Lang
Interpersonal Skills for Medical Writers	SSK3	Barry Drees and Julia Forjanic Klapproth

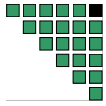
### **3. Workshop Abstracts & Workshop Leaders**



EMWA is setting up an online database of abstracts for all approved EPDP workshops and personal summaries of the workshop leaders who participate in the EPDP.

At present, most of this information can be obtained from brochures of previous conferences for workshops run at each conference. These brochures can be downloaded as PDF files from the EMWA website at [www.emwa.org](http://www.emwa.org).

## 4. **Enrolment & Fees**



### ***Enrolling in the EPDP***

---

Enrolment in the EPDP can be done together with conference registration on the conference registration form, or when applying for EMWA membership, or by contacting EMWA Head Office at any time. It is also possible to enrol in the EPDP during an EMWA conference.

Credits can normally only be accumulated for workshops completed after payment of the EPDP enrolment fee.

**Retrospective award of credits is not possible.** However, in the case of EPDP enrolment during a conference, all credit workshops taken at that conference will be eligible for credit provided the remaining requirements (see page 5) are met.

It is permissible to enrol for the foundation and the advanced levels simultaneously; each incurs a separate enrolment fee.

The enrolment fee is valid up to five years, irrespective of EMWA membership status. If sufficient credits are obtained during that period to qualify for an EMWA certificate, EPDP enrolment expires when the certificate is issued.

Participants wishing to enrol for a second foundation certificate must pay an additional enrolment fee before any credits can be accumulated towards the second certificate.

After five years, re-enrolment is required if not all credits have been obtained towards the EMWA certificate.

---

**Fees**

---

The fees for enrolment in the EPDP and for attending EPDP workshops are as follows (status October 2009):

***Foundation level:***

Enrolment in the EPDP at foundation level	€100
Attendance at each foundation workshop	€135
Discounted rate while under assessment	€0

***Advanced level:***

Enrolment in the EPDP at advanced level	€100
Attendance at each advanced workshop	€210
Discounted rate while under assessment	€140

Workshops are only open to EMWA conference attendees.

Please note that credit workshops carry the above fees whether or not the participant intends to gain credit for the workshop.

Details of fees for non-credit workshops and seminars that may be also offered during EMWA conferences (see page 6) are provided on the conference registration forms.