IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Medical Writing for Medical Devices

16-17 June 27
+ 1-2 December 27

How to produce quality regulatory documents including the clinical evaluation report (CER).

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

Writing for medical devices has its own particular skill set and, with important regulatory changes in the industry, all those involved in medical writing face a challenge to ensure they have the necessary expertise and resources to fulfil the requirements of the new regulation.

This comprehensive course has been designed to provide you with a thorough understanding of the essential aspects of medical writing, with a particular focus on medical devices. Practical exercises and discussion will consolidate learning, and helpful tips and techniques from experts in the field of medical writing and medical devices will enhance your knowledge.

Benefits of attending

- **Learn** how to prepare a document that is linguistically and stylistically appropriate
- **Understand** the effective use of visual elements such as tables, graphs and flow charts
- **Examine** the content and structure of the CER – an integral part of the submission process
- **Be** fully aware of what a Notified Body is looking for in your clinical evaluation

Who should attend?

- Medical device professionals responsible for preparing, writing and completing a CER
- Medical writers producing reports for medical device manufacturers
- Regulatory affairs personnel involved in preparing scientific documentation
- Medical device personnel who require a fundamental understanding of what is required when drafting scientific reports for their products
- Contract research organisations (CROs)
- R&D professionals

Programme

Day 1

Overview of writing and editing documents

- Substantive and technical aspects
  - Considering logic, text flow, wordiness and accuracy
  - Looking at the details such as language editing, abbreviations and acronyms
  - Preparing a clear message for the intended reader

Regulations applicable to the clinical evaluation of a medical device

- Introduction to the European Medical Device Regulation (MDR)
- Guidance documents for clinical evaluations – what is required?
- Notified Body expectations

Writing regulatory documents

- Do different audiences and documents require different approaches?
- Corresponding with the authorities

Systematic literature searches for the CER

- Effective search strategies
- Deciding on what source data is required
- State of the art

Aspects of English

- Common errors in English that should be avoided
- Brief overview of key punctuation points affecting meaning and readability

Day 2

Improving readability – be kind to your reader

- Structuring texts
- In terms of language, how perfect do regulatory documents need to be?

Structure and content of the CER

- What is required to meet the regulation?
- Contents of a CER
- Conducting a clinical evaluation

CER case study workshop

- Deciding on what source data is needed

Introduction to other medical device clinical regulatory documents

- PMCF plan and report
- Clinical investigation plan and report

Proofreading essentials

- Final checks – not just a spell check
- Practicalities, tips and tools

Key take-home messages

Presenters



Barbara Grossman

Barbara Grossman has a passion for proofreading, quality control, and education. She is a biochemist by training and a medical writer, editor and teacher by profession, with 20+ years' experience 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 contract research organisation, working in a wide range of therapeutic areas. She has given professional development training at educational institutions and organisations such as the DIA (Drug Information Association – Europe and USA), EMWA (European Medical Writers Association) and NICE (National Institute for Health and Care Excellence), and has led many company-internal training courses.

Barbara is an honorary member of EMWA, was Treasurer 1998–2005, has been an EMWA workshop leader since 2001, served on EMWA's Education Committee 2010–2018, was the Education Officer for 2 years until 2016, and was EMWA's President for 1 year until May 2020. In addition, she is an Associate Editor of Medical Writing, EMWA's journal.



Mary-Ann Preston

Mary-Ann Preston is the EMEA manager for medical writing services at NAMSA, a medical research organization providing full-service support throughout the product development process for medical devices, diagnostics, and combination products.
Mary-Ann is responsible for a team of medical writers who prepare clinical evaluation reports (CER), performance evaluation reports (PER), and other documents in accordance with regulatory requirements (e.g. Medical Device Regulation and In vitro Diagnostic Regulation), various guidance (e.g. MEDDEV 2.7/1 revision 4 and medical device coordination group documents) as well as other applicable documents and standards. She has extensive experience in the critical assessment and interpretation of technical, scientific, and clinical data for CERs, PERs, literature reviews, scientific reports, and regulatory submissions. Utilizing her strong background within the medical devices industry, Mary-Ann has provided regulatory consultation, remediation, and hands-on assistance to clients on all aspects of PERs and CERs.
As well as clinical expertise, Mary-Ann has over 20 years of R&D experience in medical devices. Her background includes the design, development, and management of pre-clinical research for medical devices from scoping, and proof of concept stage through to pivotal development, biocompatibility testing, and in vivo safety and performance studies for regulatory submissions. She has developed medical device expertise in the therapeutic areas of dermal wound healing, sports medicine, and orthopaedics.
Mary-Ann is a biochemist and cell biologist by training, with a Ph.D. in dermal wound healing and scarring.
Before joining NAMSA, she held various senior roles at another consultancy and a leading manufacturing company, Smith & Nephew.

Course dates

16-17 June 27	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 17262*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 21 Apr**
1-2 December 27	**Live online** 09:30-17:00 **UK (London)** (UTC+00) *Course code 17527*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 06 Oct**

How to book

Online:
ipi.academy/2469

Alternatively contact us to book, or if you have any queries:

Email:
info@ipiacademy.com

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **30% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

Fee
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

Please note
IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

Terms and conditions
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Reviews

★★★★★

Really fantastic and loved the speakers keep all the delegates engaged. Especially not being a native English speaker, i really enjoyed the [time taken] throughout the session, which was very practical in day to day work as medical writer

RamaKrishnaChaitanya Aluri
Medical Writer
Novonordisk
Nov 25 2024

★★★★★

Janette and Barbara were both great! Very knowledgeable, personable, enthusiastic, friendly, and with fantastic presentation skills.

Kiara Batten
Senior Clinical Trial Manager
Odin Vision
Mar 13 2024

★★★★☆

I thoroughly enjoyed the webinar, particularly for its interactive elements. The Q&A sessions, practice opportunities, and Pop quizzes were highlights for me, enhancing the learning experience by encouraging engagement and providing real-time feedback. These interactive parts not only made the content more relatable but also allowed for a deeper understanding of the topics discussed. The presentation was clear and well-structured, and the speakers demonstrated extensive knowledge and passion for their subject matter.

Lloyd Nunag
Clinical Trial Manager
Odin Vision
Mar 13 2024

★★★★☆

That is was so interactive - we could always ask and the presenters always has good examples from the real world to illustrate their point. Interaction with the other course participants was also really and useful. It was particularly useful for me to get input to some of the CER content: claims, CDP etc.

Linda Lerdrup
Clinical Scientific Manager
UNEEG medical
Mar 13 2024

Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:



ALEKSANDRA BEER
Tel: +44 (0)20 7749 4749
Email:
inhouse@ipiacademy.com



YESIM NURKO
Tel: +44 (0)20 7749 4749
Email:
inhouse@ipiacademy.com



Harry ALTAMONT
Tel: +44 (0)20 7749 4749
Email:
inhouse@ipiacademy.com

IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

10-12 Rivington Street
London EC2A 3DU

ipi.academy
Tel: +44 (0)20 7749 4749
Email: info@ipiacademy.com