Scientific Writing for Medical Devices

How to produce correct and top-quality scientific documents

TOPICS

• How to write a scientific document
• Correct use of language and style
• What a Notified Body looks for in your clinical evaluation
• Exercises: Clinical Evaluation Report (CER) case study
• Improving readability - being kind to your reader
• Proofreading essentials

YOUR SPEAKERS

Barbara Grossman
Hawkeye Medical Limited
GREAT BRITAIN

Kirsten Sander
ARTIMED Medical Consulting
GmbH, Kassel

13 - 14 MAY 2020 IN HANOVER
Scientific Writing for Medical Devices

**Aims and objectives**

This interactive course gives you a good understanding of the essential aspects of successful scientific writing.

You will learn how to prepare a document that is linguistically and stylistically appropriate, using suitable graphical elements such as tables, graphs and flowcharts, based on examples and best practice. Sessions on managing clinical evaluation projects will round off the intensive two-day programme.

This course will familiarise you with organisational issues and best practices in writing for medical devices. You will understand the formal requirements of writing scientific documents, how they can affect writing style, and the importance of the nuances of language.

**Who should attend?**

This course has been designed for professionals responsible for writing and compiling a clinical evaluation report or technical documentation for medical device manufacturers.

This includes medical writers working as employees of manufacturers or as a service-provider preparing a clinical evaluation report or technical documentation in medical device companies.

The practical training will benefit both beginners in scientific writing and those wishing to update their knowledge and improve their English writing skills in this specific area.

**YOUR SPEAKERS**

- **Barbara Grossman**
  Hawkeye Medical Limited
  GREAT BRITAIN
  Medical Writer and Consultant

- **Kirsten Sander**
  ARTIMED Medical Consulting GmbH, Kassel
  Clinical Research Manager / Scientific & Medical Writing

**Your benefit**

You will learn important aspects of writing and interdisciplinary preparation of medical and scientific documents through practical exercises.

Furthermore, you will also learn about style and terminology for clinical and regulatory documents and will receive tips from experts' practical experience.

**Limited number of attendees**

This course is restricted to 15 participants. This limitation, a feature of all FORUM courses, will give participants the opportunity to thoroughly discuss the complex issues addressed in this programme.

We recommend advance registration of at least 30 days.

**Workshop language**

Since the course will be held in English, a good working knowledge of the language is required.
Your programme on 13 and 14 May

Day 1: 09:30 - 17:30

Overview of writing & editing documents
Barbara Grossman
- Substantive & technical aspects

Medical writing & the clinical evaluation of a medical device
Kirsten Sander
- Introduction to the European medical device regulations & guidelines
- How the clinical evaluation & clinical evaluation report (CER) are related & the role of the medical writer

Writing regulatory documents
Barbara Grossman
- Do different audiences & documents require different approaches?
- Corresponding with the authorities

Aspects of English
Barbara Grossman
- Common errors in English that should be avoided
- Brief overview of key punctuation points affecting meaning & readability

Day 2: 09:00 - 17:30

Structure & content of the CER - MEDDEV 2.7/1 rev. 4 guideline
Kirsten Sander
- Source documents, how to acquire them & safety data

Improving readability - being kind to your reader
Barbara Grossman
- Structuring texts
- How perfect do regulatory documents need to be in terms of language?

CER: Systematic literature searches
Kirsten Sander
- Effective search strategies & effectiveness of search strategies

CER case study
Kirsten Sander
- Deciding on what source data are needed & finding the source data
- Group exercise

Introduction to other medical device clinical regulatory documents
Kirsten Sander
- PMCF plan & report
- Clinical investigation plan & report
- FMEA report (equivalent to RMP)

Proofreading essentials
Barbara Grossman
- Final checks - not just a spellcheck
- Practicalities, tips and tools
REGISTRATION FORM

Yes, I will attend

☐ Scientific Writing for Medical Devices
   13 - 14 May 2020 in Hanover

☐ Yes, I agree that FORUM Institut may inform me about events by:
   □ email; and/or □ telephone.
   I may withdraw my consent at any time.

Date and venue
13 - 14 May 2020 in Hanover

DORMERO Hotel
Hildesheimer Str. 34-38 · 30169 Hanover
Tel. +49 511 544-200 · Fax +49 511 544 2020-20

Fee
€ 1990.00 (+ German VAT)
The fee includes course documentation (including free download) as well as refreshments, lunch and a certificate. You will receive an invoice as well as confirmation.

Course times
Registration: 09:00 - 09:30
Day 1: 09:30 - 17:30
Day 2: 09:00 - 17:30

CANCELLATION POLICY

Our general terms and conditions (as of 1 January 2016) apply and are available upon request. We can send them to you at any time. Alternatively, you can access them online at www.forum-institut.com/t&c

YOUR CONTACT

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