Course

FORUM

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
Medical Writer and Consultant
Hawkeye Medical Limited,
GREAT BRITAIN

Gerard McGregor, PhD
Principal Medical Writer
Trilogy Writing & Consulting GmbH
Frankfurt, GERMANY

18 — 19 September 2019 in Munich

Scientific Writing for Medical Devices

Aims and objectives

This interactive course gives you a good understanding of the essential aspects of successful scientifc 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 scientifc 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 preparing, 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.

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.

Your speakers

Barbara Grossman
Medical Writer and Consultant
Hawkeye Medical Limited,
GREAT BRITAIN

Gerard McGregor, PhD
Principal Medical Writer
Trilogy Writing & Consulting GmbH
Frankfurt, GERMANY

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.

Workshop language

Since the course will be held in English, a good working knowledge of the language is required.

Your programme on 18 and 19 September 2019

Day 1: 09:30-17:30

Introduction and welcome

Overview of writing and editing documents
Barbara Grossman

- Substantive and technical aspects

Medical writing and the clinical evaluation of a medical device
Gerard McGregor

- Introduction to the European medical device regulations, directive and guidelines
- How the clinical evaluation and clinical evaluation report (CER) are related and the role of the medical writer

Writing regulatory documents
Barbara Grossman

- Do different audiences and 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 and readability

Day 2: 09:00-17:30

Structure and content of the CER - MEDDEV 2.7/1 rev. 4 guideline
Gerard McGregor

- What type of writing is needed?
- Source documents and 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

Systematic literature searches for the CER
Gerard McGregor

- Effective search strategies and effectiveness of search strategies

CER case study
Gerard McGregor

- Deciding on what source data are needed

Introduction to other medical device clinical regulatory documents
Gerard McGregor

- PMCF plan and report
- Clinical investigation plan and report
- FMEA report (equivalent to RIM)

Proofreading essentials
Barbara Grossman

- Final checks - not just a spellcheck
- Practicalities, tips and tools

We recommend advance registration of at least 30 days.

Registration under service@forum-institut.com or Fax +49 6221 500-555

Registration Form

Yes, I will attend the Course
☐ Scientific Writing for Medical Devices

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

Name

Position, department

Company

Street

Post code, city, country

Tel. no.

E-mail

Contact person at office

Date, signature

FI8417/0/0/0/0/0

How to register

- **Registration: +49 6221 500-500**
- **Conference no.: 19 09 922**

- **Website:**
www.forum-institut.com

- **Date and venue**
18 – 19 September 2019 in Munich
HYPERION Hotel Munich
Truderinger Str. 13 · 81677 Munich
Tel. +49 89 909070200 · Fax

- **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

Any Further Questions?

Please feel free to contact me if you have any questions.

Ute Akunzius-Jehn
Conference Manager
Tel. +49 6221 500-685
u.akunzius-jehn@forum-institut.de

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