

# Scientific Writing for Medical Devices

How to produce correct and top-quality scientific documents

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## 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

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## 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

# 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 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



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## 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.

## 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

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

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Position, department

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Company

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Street

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Post code, city, country

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Tel. no.

\_\_\_\_\_  
E-mail

\_\_\_\_\_  
Contact person at office

\_\_\_\_\_  
Date, signature

## 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

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## 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](http://www.forum-institut.com/t&c)