Seminar

FORUM

Scientific Writing and Reviewing in Regulatory Affairs

Update your English writing skills - with many practical exercises

Topics

- Free writing versus regulatory restrictions
- Writing and reviewing regulatory documents
- Editing and proofreading documents
- Package leaflet - regulatory linguistic restrictions and user-friendly writing
- Good writing skills - example: clinical overviews and summaries

Update your English writing skills - with many practical exercises!

Your speakers

Dr. Jörg Fuchs
PAINT-Consult®,
Jena

Barbara Grossman
Hawkeye Medical Limited
Medical Writing &
Consultancy,
GREAT BRITAIN

9 — 10 April 2019 in Frankfurt

Scientific Writing and Reviewing in Regulatory Affairs

Aims and objectives

After completing this seminar, participants will be aware of the key regulatory requirements when preparing texts, with a greater awareness of the importance of proper English writing, reviewing and proofreading processes.

Practical examples regarding the English wording in package leaflets and clinical overviews and summaries complete this seminar.

Who should attend?

This seminar is intended for all those working in regulatory departments in the human and veterinary pharmaceutical and medical device industries with basic experience in writing, reviewing or proofreading regulatory documents in English.

Participants should have good English reading and writing skills and a basic knowledge of regulatory documentation.

This seminar is restricted to 15 participants.

CTD knowledge required?

If you need basic knowledge of the content and structure of the (e)CTD, we recommend our 'Common Technical Document & eCTD' e-learning course, which will address both the full and the abridged dossier application formats. Further information may be obtained by entering 1912222 in the search form on our website.

Your speakers

Dr. Jörg Fuchs

PAINT-Consult®, Jena

Managing Director,
User Testing Consultant

Barbara Grossman

Hawkeye Medical Limited Medical Writing & Consultancy, GREAT BRITAIN

As well as a passion for proofreading and quality control, Barbara has more than 20 years experience of medical writing and editing in the pharmaceutical industry. Before starting her own medical writing and consultancy business, she built up and managed the medical writing group at Covance. Barbara has hands-on experience of preparing a variety of clinical documents, and has managed several large writing programmes. Barbara is a Fellow of EMWA and was the Education Officer for 2 years until May 2016. In addition, she is an Associate Editor of Medical Writing, EMWA's journal.

Update your writing skills

Troughout the days: practical hands-on exercises

Day 1: 10.00 - 17.30

> 10:00
Introduction
Beate Beime, Barbara Grossman

> 10:15
Overview of writing and editing documents
Barbara Grossman

- Basics of writing and editing - fine-tuning within and across documents
- Considering the reader

[one 15 min. coffee break mid-mordning]

> 12:45 Lunch

> 14:00
Free writing versus regulatory restrictions
Barbara Grossman

- Linguistic restrictions due to regulatory specifications
- Use of drug dictionaries
- Understanding medical concepts and their correct use
- Authority requests

> 14:45
Writing and reviewing regulatory documents
Barbara Grossman

- Target audiences
- Different approaches for different documents?
- Common errors in English that must be avoided
- Corresponding with the authorities

[one 15 min. coffee break mid-afternoon]

Day 2: 9.00 - 17.00

> 09:00
Writing in English for regulatory affairs
Barbara Grossman

- Aspects of English including:
  - Punctuation
  - Word order
  - Tense
  - Passive and active voice

> 11:00 Coffee break

> 11:15
How to write a package leaflet in English
Dr Jörg Fuchs

- Patient-friendly language
- Formatting
- Quality review of documents ('QRD') requirements
- Tables and figures; Proper English

> 12:45 Lunch

> 14:00
Good writing and reviewing skills in regulatory documents
Barbara Grossman

- Improving readability including practical exercises such as:
  - Edit, rewrite or leave as is?
- In terms of languages, considering how perfect documents need to be
- Dos and dont`s in clinical overviews and summaries
- Proofreading essentials including:
  - Final checks - not just a spell check
  - Practicalities, tips and tools

[one 15 min. coffee break mid-afternoon]

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

Registration Form

Yes, I will attend the seminar
- ☐ Scientific Writing and Reviewing in RA
- ☐ e-Learning (1912222)

☐ 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

How to register

- **Registration: +49 6221 500-500**
- **Conference no.: 19 04 233**

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

- **Date and venue**
9 – 10 April 2019 in Frankfurt
Day 1: 10:00 - 17:30; Day 2: 09:00 - 17:00
relexa hotel
Lurgiallee 2 · 60439 Frankfurt
Tel. +49 69 95778-0 · Fax +49 69 95778-876

- **Fee**
€ 1790.00 (+ 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.
- Fee e-learning:
€490.00 (+ German VAT)
e-Learning: Common Technical Document & eCTD (Conf.-no. 1912222) - This fee is only valid in combination with the above mentioned seminar.

Any Further Questions?

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

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Cancellation Policy

Our general terms and conditions apply (as of 1 January 2016) and are available upon request. We can send them to you anytime or you can find them on the internet at www.forum-institut.com/t&c