SEMINAR

FORUM
40 YEARS

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

YOUR SPEAKERS

Dr Jörg Fuchs
PAINT-Consult®,
Jena, GERMANY

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

17 - 18 FEBRUARY 2020 IN FRANKFURT

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 the webcode 2012220 on our website.

Your speakers

Dr Jörg Fuchs

PAINT-Consult®,
Jena, GERMANY

Dr Jörg Fuchs is our expert in user-friendly medical information and readability tests. He is founder and head of PAINT-Consult®, a company that specialises in readability and usability tests, medical information, research studies and more in the field of regulatory affairs. Having completed his pharmacy studies at the University of Greifswald in 1996, he immediately applied himself to conducting research in improving and testing patient information leaflets, which led to a doctorate at the Humboldt-Universität zu Berlin. This research has been ongoing at the Department of Drug Regulatory Affairs at the University of Bonn since 2005.

Barbara Grossman

Hawkeye Medical Limited
Medical Writing & Consultancy,
GREAT BRITAIN

Barbara Grossman has a passion for proofreading, quality control, and education. She started Hawkeye Medical Limited, a medical writing and consultancy business, after working for a medical publishing company and then a contract research organisation, where she built up and managed its medical writing group. Barbara runs professional development training for companies and educational institutions. She has had many roles in EMWA: workshop leader since 2001, Treasurer 1998–2005, member of the Education Committee 2010–2018, Education Officer 2014–2016. She was awarded an EMWA fellowship in 2005 and is currently EMWA President. In addition, Barbara 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

Introduction
Barbara Grossman

Overview of writing and editing documents
Barbara Grossman

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

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

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

Day 2: 10:00 - 17:00

Writing in English for regulatory affairs
Barbara Grossman

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

How to write a package leaflet in English
Dr Jörg Fuchs

- Patient-friendly language and volume of text
- Formatting and typography
- Regulatory specifications, such as QRD requirements
- Tables and figures; proper English

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

Scientific Writing and Reviewing in Regulatory Affairs

REGISTRATION UNDER

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REGISTRATION FORM

Yes, I will attend

☐ Scientific Writing and Reviewing in Regulatory Affairs (Webcode 2002233)

☐ e-Learning (Webcode 2012220)

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

Name

Position, department

Company

Street

Post code, city, country

Tel. no./Fax no.

E-mail

Contact person at office

Date, signature

Date and venue
17 - 18 February 2020 in Frankfurt

Day 1: 09:30 registration
10:00 - 17:30 seminar
Day 2: 09:00 - 17:00 seminar

Steigenberger Airport Hotel
Unterschweinstiege 16
60549 Frankfurt
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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. 2012220) - This fee is only valid in combination with the above mentioned seminar.

CANCELLATION POLICY

Our general terms and conditions (as of1 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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