ONLINE-SEMINAR

FORUM

Scientific ENGLISH Writing and Reviewing in Regulatory Affairs

Throughout both days: lectures, practical hands-on exercises and text review sessions

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

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

Dr Jörg Fuchs
PAINT-Consult®,
Jena, GERMANY

29 - 30 SEPTEMBER 2021 ONLINE

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.

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 2112220 on our website.

YOUR SPEAKERS

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

Associate Editor of Medical Writing

Dr Jörg Fuchs
PAINT-Consult®,
Jena, GERMANY

Managing Director, User Testing Consultant

Your benefits

- Two highly experienced speakers
- Throughout the days: practical hands-on exercises in the virtual conference room
- We work with whiteboards, Zoom breakout rooms...
- Practical examples regarding the English wording in package leaflets and clinical overviews and summaries

Quality guaranteed!

We follow the IMI quality criteria and, as a signatory, we are an active partner in further developing and optimising the quality standards. An aggregate evaluation of participants' feedback on all FORUM's healthcare training courses (evaluation period from 01.2020 – 12.2020) produced a result of 1.7 (based on a school grading system of 1–6).

Update your writing skills

Throughout the days: practical hands-on exercises

Day 1: 10:00 - 17:00

Introduction round using the Zoom whiteboard

Overview of writing and editing documents

Barbara Grossman

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

Writing and reviewing regulatory documents

Barbara Grossman

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

Day 2: 09:00 - 17:00

Free writing versus regulatory restrictions

Dr Jörg Fuchs

- Regulatory specifications, such as QRD requirements
- Linguistic restrictions due to regulatory specifications
- Understanding medical concepts and their correct use
- Authority requests

How to write a package leaflet in English

Dr Jörg Fuchs

- Patient-friendly language and volume of text
- Formatting and typography
- Understanding medical concepts and their correct use
- Tables and figures; proper English

Writing in English for regulatory affairs

Barbara Grossman

- Aspects of English including punctuation; word order, tense, passive and active voice

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 ENGLISH Writing and Reviewing in Regulatory Affairs

REGISTRATION UNDER

service@forum-institut.com **Tel. +49 6221 500-500**
www.forum-institut.com **Fax +49 6221 500-555**
Webcode 2109232

REGISTRATION FORM

Yes, I will attend

☐ Scientific ENGLISH Writing and Reviewing in Regulatory Affairs (Webcode 2109232)

☐ e-Learning: Common Technical Document & eCTD (Information and programme on our website with the webcode 2112220)

☐ 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
29 - 30 September 2021
Day 1: 10:00 - 17:00; Day 2: 09:00 - 17:00
You may dial in 30 min. before the session

Fee seminar (Webcode 2109232)
€ 1,790.00 (+ German VAT) The fee includes course documentation for download as well a certificate.

Fee e-learning (Webcode 2112220)
€ 490.00 (+ German VAT) - This fee is only valid in combination with the above mentioned seminar.

This is how it works

- The online seminars are live and interactive.
- They are held and controlled directly by our speaker.
- You may take part in the seminar from anywhere using your end device.
- You will see the presentation and listen to our speaker's lecture using Internet telephony (VoIP) or even a normal telephone connection.
- And you can also ask questions live, using the chat function.

CANCELLATION POLICY

Our general terms and conditions (as of 20 November 2019) 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

Dr. Henriette Wolf-Klein
Head of Department
Tel. +49 6221 500-680
h.wolf-klein@forum-institut.de