Seminar

QualitecFarma® REGULATORY & BUSINESS STRATEGIES FORUM

CMC Documents: Scientific Writing for Regulatory Submission

Topics

- CMC Writing: key elements and mandatory requirements
- Structure and presentation of Module 3 and the Quality Overall Summary
- English writing skills
- Avoiding common language pitfalls
- Cross-checking and avoiding questions from Health Authorities

Workshop:
How to write the Module 3

Your speakers

Birgit Heilmann
Bayer Pharma AG,
Leverkusen

Dr Silvia Rogers
MediWrite GmbH,
Basel

17 October 2017 in Köln

CMC Documents: Scientific Writing

Aims and objectives

Our seminar will provide you with practical tools to help you become more comfortable writing the CTD's CMC documents.

After a short update on grammar, English standards and style, you will be better equipped to write Module 3 and the Quality Overall Summary: you will be able to present data clearly and in compliance with the regulations, and you will be able to sew a "golden thread" through your CMC documents.

In addition, English writing skills will be a part of your repertoire, enabling you to deal with the difficulties posed by the English language to both native and non-native speakers. Having applied your writing skills to practical exercises, you will be able to write the drug substance as well as the drug product sections using sophisticated English.

Last but not least you will learn to cross-check the CMC documents prior to submission and to avoid questions from Health Authorities.

Who should attend?

This seminar addresses the needs of those working in the pharmaceutical industry. It will particularly benefit those:

- writing and reviewing international CMC documents; and
- wanting to optimise their English writing skills.

Participants should have prior knowledge of the content and structure of Module 3 and the Quality Overall Summary.

Your speakers

Birgit Heilmann
Bayer Pharma AG, Leverkusen

Head of Product Documentation
Pharmaceuticals Division - Quality

Dr Silvia Rogers
MediWrite GmbH, Basel

Pharmacologist
Extensive R&D experience as a project manager. Today owner of MediWrite, Medical and Scientific Writing in Basel, and lecturer at the University of Basel.

Quality guaranteed!

IMI (Innovative Medicines Initiative) defined quality criteria for professional training and education. We follow these 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 10.2015 - 09.2016) produced a result of 1.7 (based on a school grading system of 1-6).

Your programme

> 9.00

Structure and presentation of Module 3 and the Quality Overall Summary

Birgit Heilmann

- CMC writing: individual freedom of writing vs mandatory and formal requirements
- Generation and presentation of data
  - Roles and responsibilities
  - "Good Document Practice"
  - Use of GMP documents for submission

> 10.00 Coffee break

> 10.15

English Writing Skills for Module 3 and the Quality Overall Summary

Dr Silvia Rogers

- Key elements of good CMC writing
  - Punctuation
  - Word order (syntax) and subject-verb agreement
  - Correct use of verb tenses
  - Active versus passive writing
  - Abbreviations and acronyms
  - Using capital letters
  - Consistent spelling (American versus British)
  - Expressing numbers
- Best practice
  - Avoiding common misconceptions, jargon and redundancies
  - Writing ethics

> 12.30 Lunch

> 13.45

Language pitfalls to be avoided in CMC modules

Dr Silvia Rogers

- For native English speakers
- For non-native English speakers

> 14.30 Coffee break

> 14.45

Putting what we have learned into practice

Dr Silvia Rogers

- Studies and exercises

> 16.00

Consistent CMC documents and cross-checks

Birgit Heilmann

- Consistent and compliant CMC documents
- Cross-checking Module 3: essentials and fine-tuning within and across CMC documents
- Avoiding questions from Health Authorities
  - Do's and don'ts
  - Examples of critical sections

> 17.00 End of seminar

CMC Documents: Scientific Writing

Registration recommended 30 days in advance

Registration under
formacion@qualitecfarma.com or
Telf.: +34 91 372 83 99

Registration Form

Yes, I will attend the seminar
☐ CMC Documents: Scientific Writing for Regulatory Submission

Name

Position/Department

Company

Street

Postal Code/City/Country

Tel. No.

E-Mail

Contact person at office

Date, Signature

How to Register

Registration: +34 91 372 83 99

Conference No. 17 10 272

Internet:
www.qualitecfarma.com

Date / Venue:
Tuesday, 17 October 2017 in Koln
8.30 registration; 9.00 - 17.00 Seminar
Pullman Cologne
Helenenstr. 14 · 50667 Koln
Tel. +49 221 275-0 · Fax +49 221 275-2205

Fee:
€ 990.00 (+ German VAT)
The fee includes course documentation (incl. free download) as well as mid-session refreshments, lunch and certificate. Invoice and confirmation will be forwarded to you.

Hotel accommodations:
A limited number of rooms have been reserved at the hotel and are subject to availability. Please book at least six weeks prior to the seminar to obtain a hotel room at the discounted rate. All bookings should be made directly with the hotel quoting FORUM Institut and the Course No.

Any Further Questions?

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

Pablo García
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Cancelation Policy

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