Workshop

FORUM

Medical Writing in Pharmacovigilance

Update your English writing skills - with many exercises!

Topics

- Key pharmacovigilance definitions and concepts
- Scientific, technical or lay language
- Risk management plan:
  Contents, structure & requirements
- Development & Periodic safety update reports:
  Practical exercises
- Common pitfalls

Register soon! Limited number of attendees!

Your speaker

Dr Tiziana von Bruchhausen
Senior Pharmacovigilance Writer
Boehringer Ingelheim Pharma GmbH & Co. KG

4 — 5 June 2019 in Berlin

Medical Writing in Pharmacovigilance

Aims and objectives

This two-day workshop provides an introduction to medical writing for pharmacovigilance, as well as insights into several relevant safety documents. You will learn regulatory requirements and how to apply guidelines to prepare pharmacovigilance documents.

In addition, you will learn important aspects of writing and interdisciplinary preparation of pharmacovigilance documents through practical exercises. You will also learn about style and terminology for pharmacovigilance documents (for regulatory, medical and lay public) and will receive tips from experts' practical experience.

Who should attend?

This workshop is intended for those who work in the pharmaceutical industry and are new to pharmacovigilance writing. Participants should have some basic knowledge of the drug development process, of regulatory documentation and of pharmacovigilance.

Testimonials

- "It even has exceeded the expectations as there was a lot of room for discussion/questions."
- "Excellent comprehensive course on PV documents for medical writers."
- "Great speaker, very practical, learning's directly applicable."

Your speaker

Dr Tiziana von Bruchhausen

Senior Pharmacovigilance Writer,
Boehringer Ingelheim Pharma GmbH & Co. KG

Tiziana von Bruchhausen specialised over the last 10 years in pharmacovigilance and gained extensive hands-on experience with the EU Pharma Package. She worked as a pharmacovigilance writer for mid-sized and large pharmaceutical companies, covering various roles in a contract research organization and as a freelance writer.

She is currently working as a senior pharmacovigilance writer at Boehringer Ingelheim. Her tasks and responsibilities cover pre- and post-submission activities related to the global strategic planning and the preparation of pharmacovigilance documents with a focus on RMPs, PSURs and their assessment reports.

Tiziana is an active volunteer at the European Medical Writers Association (EMWA), where she chairs the Pharmacovigilance Special Interest Group Committee. She was Vice President of EMWA in 2017 and has taken over the Presidency in May 2018.

Your programme for both days

Overview of contents

- Key pharmacovigilance definitions
- Development safety update report (DSUR)
- Risk management plan (RMP)
- Periodic safety update report (PSUR)/periodic benefit-risk evaluation report (PBRER)
- English for regulatory documents
- Medical writing tips
- Practical exercises

Introduction to pharmacovigilance

- Definition of key terms relevant for pharmacovigilance documents

Pharmacovigilance documents in the life cycle of a medicinal product: scope and role

DSUR - RMP - PSUR/PBRER

- Regulatory requirements
- Guidelines
- Contents
- Structure and template
- Role of the pharmacovigilance writer
- Interface with other functions; planning aspects
- Focus, overlap, timing of DSUR, RMP, and PSUR/PBRER
- Practical exercises

English for regulatory documents

- Style and terminology
- Scientific, technical, and lay language
- Style insights
- How to enhance readability
- Common errors and practical exercises

Questions, discussion and conclusions

Registration recommended 30 days in advance!

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

Registration Form

Yes, I will attend the Workshop
☐ Medical Writing in Pharmacovigilance

☐ 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

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How to register

- **Registration: +49 6221 500-500**
- **Conference no.: 19 06 202**

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

- **Date and venue**
4 – 5 June 2019 in Berlin
Day 1: 10:00-17:30; Day 2: 08:30-16:00
Mercure Hotel MOA Berlin
Stephanstr. 41 · 10559 Berlin
Tel. +49 30 394043-0 · Fax +49 30 394043-999

- **Fee**
€ 1690.00 (+ 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.

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.de/agb_en