Workshop

QualitecFarma® REGULATORY & BUSINESS STRATEGIES FORUM

Advanced Pharmacovigilance Writing and Management

Topics

- RMP management in the post-authorisation phase
- Role of the pharmacovigilance writer beyond professional writing
- Impact of EU assessment reports on RMPs and PSURs
- Effective global management and harmonisation of RMPs and PSURs
- Additional risk minimisation measures

Insights into RMP and PSUR preparation, assessment and regulatory management

Your speakers

Dr Sabine Jeck-Thole
Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim

Dr Harriet Palissa
-requested-
Senior Expert Pharmacovigilance, Bonn

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

17 October 2017 in Frankfurt

Advanced Pharmacovigilance Writing and Management

Aims and objectives

This workshop provides insights into RMP and PSUR preparation, assessment and regulatory management.

After completing the seminar, you will:

- be able to handle your RMP updates correctly;
- be familiar with the tasks and duties of a QPPV in the lifecycle of PSURs and RMPs;
- know the tips and tricks for strategic planning and project coordination as a pharmacovigilance writer;
- be able to handle EU assessment reports; and
- have a good understanding of the planning, preparation and management of additional risk-minimisation measures.

Insights into the global management of pharmacovigilance documents round off this seminar.

Who should attend?

This workshop is intended for those working in the pharmaceutical industry already having profound knowledge of pharmacovigilance writing (with a focus on PSUR and RMP). QPPVs and people responsible for national pharmacovigilance are also invited to join in the intensive discussion.

Your speakers

Dr Sabine Jeck-Thole
Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim

EU QPPV and Head Regional Pharmacovigilance

Dr Harriet Palissa
-requested-

Senior Expert Pharmacovigilance, Bonn

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

Senior Pharmacovigilance Writer

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 10.2015 - 09.2016) produced a result of 1.7 (based on a school grading system of 1-6).

Your programme

> 9.00
Introduction to the workshop

> 9.15
How the medicinal product's life-cycle is reflected in PV activities

- Overview of regulatory requirements for pharmacovigilance documents in the medicinal product s life cycle
- Role of RMPs and PSURs and evaluation of the respective activities in the context of QPPV tasks and duties

> 9.45
Management in the post-authorisation phase

- RMP submission requirements
- Significant changes in RMPs
- Regulatory handling of RMP Updates

> 10.30 Coffee break

> 10.45
Practical exercise: Role of the PV writer beyond professional writing

- RMPs and PSURs: strategic planning and project coordination throughout the medicinal product's lifecycle

> 12.15
Global pharmacovigilance activities: QPPV overview

- Regulatory processes
- Interdisciplinary responsibilities
- Quality management aspects

> 12.30 Lunch

> 13.30
RMP and PSUR assessment reports

- Outcomes of assessment reports
- Impact of EU assessment reports on RMPs and PSURs; management of PSURs as global documents

> 14.00
Discussion: Insights into pharmacovigilance writing

All speakers

- Tips and tricks from the PV writer, QPPV and health authority

> 14.30
RMPs and PSURs: global management

- Effective global management
- Harmonisation of RMPs and PSURs

> 15.00 Coffee break

> 15.15
Practical exercise: Additional risk minimisation measures

- Global and local management

> 16.30
RMP and additional risk minimisation measures

- Principles, planning and preparation of educational material
- Authorities' services and website

> 17.00 End of workshop

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

Registration Form

Yes, I will attend the Workshop
☐ Advanced Pharmacovigilance Writing and Management

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 10 201

Date / Venue:
Tuesday, 17 October 2017 in Frankfurt
8.30 registration; 9.00 - 17.00 seminar
Steigenberger Airport Hotel
Unterschweinstiege 16 · 60549 Frankfurt
Tel. +49 69 6975-0 · Fax +49 69 6975-2505

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.

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Conference Manager
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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