Seminar

QualitecFarma® REGULATORY & BUSINESS STRATEGIES

FORUM

Masterclass EU QPPV

Current challenges for the Qualified Person for PV

Topics

- Efficient delegation and cooperation with your deputy
- How to maintain oversight of multinational PV activities
- Sustainable collaboration with other departments
- Mergers and acquisitions: how do you ensure that PV-compliance is not compromised?
- Workshop: Resource planning in pharmacovigilance

Your key to success with many practical tips for your daily work.

Your speakers

Dr Katharina Caspary
Horizon Pharma GmbH,
Mannheim

Dr Monica Rusu
Abbott Laboratories GmbH,
Hannover

25 September 2017 in Frankfurt

Aims and objectives

The duties of the European Qualified Person for Pharmacovigilance are diverse and challenging. This is why our advanced seminar will provide you with practical tips and hints for your work, and further equip your available toolbox.

After the seminar, you will be able to:

- set up an efficient QPPV delegation and deputy system;
- work more effectively together with other important departments to ensure the quality of your PV system;
- maintain oversight of multinational PV acitivities; and
- plan the resources you need in a changing regulatory environment.

Who should attend?

This seminar is intended for those working in the pharmaceutical industry that have an extensive regulatory background in terms of the QPPV role and now would like to improve their daily processes.

The following will especially benefit from this seminar:

- EU QPPVs and their deputies;
- National Persons Responsible for Pharmacovigilance;
- Heads of Pharmacovigilance; and
- consultants providing QPPV services.

Your speakers

Dr Katharina Caspary

Horizon Pharma GmbH, Mannheim

Director Pharmacovigilance;
Medical doctor with profound experience in various areas in the pharmaceutical industry. Proven track-record of successful strategic roles in pharmacovigilance and clinical research and well-experienced in cross-functional projects as well as M&A across Medical Affairs, Regulatory, Marketing & various outside parties.

Dr Monica Rusu

Abbott Laboratories GmbH, Hannover

Director PV Governance & EU QPPV, Global Pharmacovigilance Innovation & Development, Established Pharmaceuticals

International courses

Are you interested in our international education programme? We provide a variety of specialised courses for the healthcare industry.

Quality guaranteed!

We follow the IMI quality criteria. An evaluation of participants' feedback on our healthcare courses produced a result of 1.7 (school grading system of 1-6).

Your programme

> 9.00 Welcome and Introduction round

> 9.15

National Person Responsible for PV vs EU QPPV

Dr Monica Rusu

- Regulatory background in Europe
- Responsibilities in SMEs and large companies
- Liability
- How to handle interfaces

> 10.00 Coffee break

> 10.15

Workshop: Efficient delegation

Dr Monica Rusu

- Mandatory and obligatory tasks to delegate
- Correct documentation
- Cooperation with your deputy
- Establish your own monitoring system

> 12.00 Lunch

> 13.00

How to maintain oversight of multinational PV activities

Dr Katharina Caspary

- PSMF - the most important document?
- How to keep up-to-date with all the national peculiarities in Europe
- Useful processes and company structures
- The correct way to handle all the data and information
- Gathering all the information from license- and PV-partners
- The QPPV's role in ensuring affiliate compliance

> 14.30

Collaboration with other departments

Dr Monica Rusu

- Important contact points in the company: Quality, Clinical, Commercial, Medical Affairs, Regulatory Affairs - best practices to ensure QPPV involvement
- Quality deficiencies: responsibility of the EU QPPV? How to organize possible recalls
- Harmonised quality system in PV, QA and Medical Affairs - a possible approach?

> 15.30 Coffee break

> 15.45

Mergers and acquisitions: How do you ensure that PV-compliance is not compromised?

Dr Katharina Caspary

- What has to be considered after an acquisition?

> 16.15

Workshop: Resource planning in Pharmacovigilance

Dr Katharina Caspary, Dr Monica Rusu

- What resources do you need for a working PV system
- Manpower, and workload

> 17.00 End of seminar

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 09 203

Date / Venue:
Monday, 25 September 2017 in Frankfurt
8.30 registration; 9.00 - 17.00 seminar
relexa hotel
Lurgiallee 2 · 60439 Frankfurt
Tel. +49 69 95778-0 · Fax +49 69 95778-876

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
Conference Manager
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Cancellation Policy

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