Seminar

QualitecFarma® REGULATORY & BUSINESS STRATEGIES FORUM

Pharmacovigilance Inspection Readiness

Strategies for successful PV Inspections in Europe

Topics

- Fundamentals: regulations, occurrence, types and aims
- Pharmacovigilance inspections in Germany and by MHRA
- What are the differences between the authorities?
- Strategic planning and preparation for a GPvP inspection
- Report, findings and follow-up measures
- Dos and don'ts, and factors of success

Be prepared for your next GPvP inspection!

Your speakers

Dagmar Gauweiler
Xendo UK Ltd,
UNITED KINGDOM

Dr Petra Lerner-Hiller
Senior PV Auditor /
PV Quality Consultant,
GERMANY

Dr Kimberley Sherwood
Senior Expert
Pharmacovigilance,
GERMANY

9 October 2017 in Frankfurt

Pharmacovigilance Inspection Readiness

Aims and objectives

In order to ensure that marketing authorisation holders comply with pharmacovigilance obligations, competent authorities conduct pharmacovigilance inspections at specific intervals. Our workshop will provide insights into the current pharmacovigilance inspection strategy in Europe.

After attending the seminar you will:

- know the differences in the inspections of the two major authorities in Europe;
- be able to plan and prepare for pharmacovigilance inspections according to the different requirements; and
- improve how you process findings during and after the inspection.

Who should attend?

This seminar will be of benefit to all those working in the pharmaceutical industry who need a deep understanding of the current pharmacovigilance inspection strategy in Europe and how to handle inspections successfully.

Limited Number of attendees

This seminar is restricted to 15 participants. This limitation, a feature of all FORUM seminars, will give participants the opportunity for a thorough discussion of the complex issues to be covered by the programme.

Your speakers

Dagmar Gauweiler

Senior Consultant, Xendo UK Ltd, UNITED KINGDOM

Dr Petra Lerner-Hiller

Senior PV Auditor / PV Quality Consultant, Darmstadt, GERMANY

Dr Kimberley Sherwood

Senior Expert Pharmacovigilance, Bonn, GERMANY

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 Welcome and Introduction Round

> 9.15
GPvP inspections - Fundamentals
Dr Petra Lerner-Hiller

- Regulations in the EU: GVP module III
- Inspection objectives
- Inspection types
- Inspection planning (scope, sites, process)
- Quality management related to inspections
- Roles of various stakeholders

> 10.15
Pharmacovigilance inspections in Germany
Dr Kimberley Sherwood

- Communication with the companies
- Inspection plan and extent
- Which are the most important documents?
- Findings: meaning of 'minor', 'major' and 'critical'
- Consequences for companies

> 11.30 Coffee break

> 11.45
Pharmacovigilance inspections by MHRA - Industry experience
Dagmar Gauweiler

- MHRA inspection department
- Communication with the companies
- Which are the most important documents?
- Findings: meaning of 'minor', 'major' and 'critical'
- Responding to inspection findings
- Consequences for companies

> 12.45 Lunch

> 13.45
Discussion round: What are the differences between the authorities?
Dagmar Gauweiler, Dr Kimberley Sherwood

> 14.15
Strategic planning and preparation of a GPvP Inspection
Dr Petra Lerner-Hiller

- Planning and preparation for inspections
- Guidance and quality documents
- Inspection readiness plan
- Importance of the PSMF
- How to prepare for an inspection - pitfalls

> 16.00 Coffee break

> 16.15
Inspection and follow-up
Dr Petra Lerner-Hiller

- Communication with the inspector
- The value of documentation and communication
- Dos and don'ts, and factors of success
- Report, findings and follow-up measures

> 17.00
CAPA Management - Resolving inspection findings
Dagmar Gauweiler

- Workshop:
  Response and CAPA management

> 17.30 End of the Workshop

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

Registration Form

Yes, I will attend the seminar
☐ Pharmacovigilance Inspection Readiness

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 10 200

Date / Venue:
Monday, 9 October 2017 in Frankfurt
8.30 registration; 9.00 - 17.30 seminar
QGREENHOTEL by Melia
Katharinenkreisel · 60486 Frankfurt
Tel. +49 69 70730-0 · Fax +49 69 70730-333

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

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