Seminar

QualitecFarma® REGULATORY & BUSINESS STRATEGIES FORUM

Set up of a Global PV Quality & Compliance System

Topics

- Set up of a global pharmacovigilance system - best practice
- PSMF - a European document going global
- Measuring the performance of the global PV system
- EU QPPV - a European role going global
- Audit and inspection readiness

Practical guidance for a global compliance and quality system in pharmacovigilance!

Your speakers

Dr Anke Feldmann
Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim

Dr Sabine Hackel
Merck KGaA, Darmstadt

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

Olga Kuhlmann
Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim

7 December 2017 in Frankfurt

Set up of a Global PV Quality & Compliance System

Aims and objectives

An effective pharmacovigilance quality and compliance system across all your affiliates and partners worldwide is necessary to comply with the individual regulatory requirements in the countries.

Our experts will provide practical hints on how to design, set up and manage such a global PV quality system. The seminar will discuss:

- the set up of a global system and tools to monitor its effectiveness;
- controlled documents and what information they should contain;
- PSMF as a global document;
- the role of the EU QPPV in a global PV system;
- how to prepare for audits and inspections; and
- how to identify and handle non-compliance.

Who should attend?

This seminar will be of benefit to all those working in the pharmaceutical industry in pharmacovigilance and partner functions who need practical guidance in establishing and managing a global quality and compliance system in pharmacovigilance.

Good knowledge of the European pharmacovigilance framework is necessary.

Your speakers

Dr Anke Feldmann
Boehringer Ingelheim Pharma GmbH & Co. KG

Head PV Compliance

Dr Sabine Hackel
Merck KGaA, Darmstadt

Head Compliance and Standards, Deputy EU QPPV, Global Drug Safety

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

EU QPPV and Head Regional Pharmacovigilance

Olga Kuhlmann
Boehringer Ingelheim Pharma GmbH & Co. KG

Head PV Audits, Inspections & Training Strategy

Quality guaranteed!

We follow the IMI quality criteria. 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 global pharmacovigilance systems

Dr Sabine Jeck-Thole

- Definition of key PV processes
- What needs to be considered; interfaces and description PV-relevant processes
- The PV system

> 9.30

Design of a global pharmacovigilance system - best practice

Dr Sabine Hackel

- Description of processes contributing to the PV system
- Facilities and equipment for global PV

> 10.30 Coffee break

> 10.45

Set up of a global pharmacovigilance system - best practice (continued)

Dr Anke Feldmann, Olga Kuhlmann

- Record management (archive)
- Quality objectives and the structure- and process-specific quality objectives
- Tools for monitoring: performance indicators for the effectiveness of the pharmacovigilance system
- Documents on organisational structures and the assignment of tasks
- Job descriptions and organisational charts
- Business continuity

> 12.15 Lunch

> 13.30

PSMF - a European document going global

Dr Sabine Hackel, Dr Sabine Jeck-Thole

- Maintenance, update frequency, contribution
- Main text vs annex
- EEA vs non-EEA
- What is required and when - renewal, MAA, inspection

> 14.15

EU QPPV - a European role going global

Dr Sabine Jeck-Thole

- Responsibilities of the MAH
- Qualifications
- Role and responsibilities
- Local QPPV

> 15.00 Coffee break

> 15.15

Measuring the performance of the global PV System

Dr Anke Feldmann, Olga Kuhlmann

- Deviations in routine processes - non-compliance
- KPIs (global and local)
- PV compliance summary and compliance review external/internal
- Global corrective and preventive activities
- Training - PV as a company commitment
- Audits: strategy and planning
- Global inspection readiness

> 17.15 End of seminar

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

Registration Form

Yes, I will attend the Workshop

☐ Set up of a Global PV Quality & Compliance System

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 12 201

Date / Venue:

Thursday, 7 December 2017 in Frankfurt
8.30 registration; 9.00 - 17.15 seminar
Hilton Frankfurt
Hochstr. 4 · 60313 Frankfurt
Tel. +49 69 13380-0 · Fax +49 69 13380-6020

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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Cancelation Policy

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