Seminar

QualitecFarma® REGULATORY & BUSINESS STRATEGIES FORUM

PV Requirements in Emerging Markets

The topics

Fokus Asia - LATAM - Russia - MENA

- Legal framework in selected emerging countries
- Similarities and differences compared to EMA regarding ADR collection and reporting
- PSMF, PSURs and RMPs – country-specific requirements
- How to integrate local PV systems into a global system
- Cooperating successfully with the emerging markets

Your speakers

Anna Kramar
Eisai LLC, RUSSIA

Raphael Pareschi
Johnson and Johnson, BRAZIL

Dr Heike Schöpper
Merck KGaA, GERMANY

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

Karin van der Auwera
Intercultural Communication Training, GERMANY

26 - 27 October 2017 in Wiesbaden

PV Requirements in Emerging Markets

Your speakers day one

Anna Kramar
Eisai LLC, RUSSIA

Regulatory Affairs and PV Manager Russia

Raphael Pareschi
Johnson and Johnson, BRAZIL

Regional Pharmacovigilance Associate Manager – LATAM

Dr Heike Schöpper
Merck KGaA, GERMANY

Head Global Drug Safety, a.i. & Drug Safety Regions

Your speakers day two

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

EU QPPV and Head Regional Pharmacovigilance

Karin van der Auwera
Intercultural Communication Training, GERMANY

Day 1: 09:00 -17:00

Think global, act local

Dr Heike Schöpper

- Where to find all the information
- Health agency interactions in non-EU countries and their global impact
- PV SOPs for PV requirements worldwide
- How to integrate local PV systems into a global system
- Cultural diversity: don't get lost in translation
- Safety Data Exchange Agreements
- PV intelligence
- Case studies

Pharmacovigilance requirements in the EAEU

Anna Kramar

- Legal background and national authorities
- Role of affiliates, external consultants and agents
- Similarities to, and differences from, EMA with regard to:
  - ADR reporting timelines
  - Patient safety in clinical trials
  - PSUR requirements
  - RMPs
  - PSMF
  - PV inspections and sanctions
- EAEU QPPV
- Practical examples
- Future trends

Your programme in detail

A detailed schedule is availabe with the Webcode 1710203

Pharmacovigilance requirements in Latin America (in the context of selected countries)

Raphael Pareschi

- Legal background and national authorities
- Role of affiliates, external consultants and agents
- Similarities to, and differences from, EMA with regard to:
  - ADR reporting timelines
  - Patient safety in clinical trials
  - PSUR requirements
  - RMPs
  - PSMF
  - PV inspections and sanctions
- Case studies
- Future trends

Intercultural know-how for the emerging markets

Karin van der Auwera

- How to talk about mistakes or disagree with someone
- Why 'truth' is a rather 'flexible' concept and how to clarify what's going on

Cooperating successfully with the emerging markets

Karin van der Auwera

- Save your deadlines: skilfully handling time spirals, 'liquid time' and the mañana mentality
- Team workers meet top-down hierarchies: navigating around the danger zones

Day 2: 09:00 -17:00

Pharmacovigilance requirements in Asia

Dr Sabine Jeck-Thole

- Legal background
- Similarities to, and differences from, EMA with regard to:
  - ADR reporting timelines
  - Patient safety in clinical trials
  - PSUR requirements
  - RMPs
  - PSMF
  - PV inspections and sanctions
- Role of affiliates, external consultants and agents
- Practical examples
- Future trends

Pharmacovigilance requirements in MENA

Dr Sabine Jeck-Thole

- Legal background
- Similarities to, and differences from, EMA with regard to:
  - ADR reporting timelines
  - Patient safety in clinical trials
  - PSUR requirements
  - RMPs
  - PSMF
  - PV inspections and sanctions
- Role of affiliates, external consultants and agents
- Practical examples
- Future trends

PV Requirements in Emerging Markets

Aim of this seminar

Regulatory expectations around risk management for medicinal products in emerging markets are competing with the stringent standards set by the ICH regions. The diversity of PV-relevant regulations call for a finely tuned balance to ensure that all PV systems employed by a company tie into a global PV matrix.

Our experts will give you a detailed update on the current legal and regulatory background and on your duties with regard to:

- ADR collection and reporting;
- PSUR and RMP requirements;
- PSMF in specific emerging countries.

Moreover, our seminar will help you create a structure to integrate your local PV system into a global system.

Who should attend

This seminar addresses the needs of those working in the pharmaceutical industry. It will particularly benefit those dealing with international pharmacovigilance issues, such as:

- drug safety managers;
- clinical trials managers and
- regulatory affairs managers.

Good knowledge of the European pharmacovigilance framework is a prerequisite.

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

Yes, I will attend the Seminar

☐ PV Requirements in Emerging Markets

Name

Position/Department

Company

Street address

Postal Code/City/Country

Tel. No.

E-Mail

Contact person at the office

Date/Signature

- **Registration: +34 91 372 83 99**
- **Conference-No. 17 10 203**
- **Date/Venue:**

26 - 27 October 2017 in Wiesbaden
NH Aukamm Wiesbaden
Aukamm Allee 31 · 65191 Wiesbaden
Tel. +49 611 576-0 · Fax +49 611 576-440

- **Fee:**

€ 1.790 (+ German VAT)
The fee includes course documentation (incl. free download) as well as midsession refreshments, lunch and certificate.
Invoice and confirmation will be forwarded to you.

- **Questions and information:**

Pablo García (Conference Manager. QualitecFarma)
Tel. +34 91 372 83 99 formacion@qualitecfarma.com

- **Cancellation Policy:**

Our general terms and conditions apply (as of 01.01.2016) 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