PV Requirements in Emerging Markets

The topics

- 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
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

PV Requirements in Emerging Markets
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.

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**Registration: +49 6221 500 555 or email: service@forum-institut.de**

Yes, I will attend the Seminar
☐ PV Requirements in Emerging Markets

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**Registration: +49 6221 500-500**

**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:**
Jessica Jegodka
Tel. +49 6221 500-696 · j.jegodka@forum-institut.de

**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