



German Pharmacovigilance Day 2015 Hot Topics in Pharmacovigilance

**Tuesday, 2nd June 2015 - InterCity Hotel Frankfurt Airport
FRANKFURT AM MAIN - Am Luftbrückendenkmal 1 - Cargo City Süd
09:30 - 17:10**

There are still important and hot topics in Pharmacovigilance to discuss despite that GVP was introduced already some time ago. These comprise e.g. different policies between CHMP, CMD(h), EMA and some national authorities, the current and future role and performance of versus qualitative/empiric signal detection, joined activities in PASS and interdependencies in RMPs, the non-conformity between company and EU- or local QPPV, the growing relevance of audits and training at PV inspections and the adequate methods of the continuous benefit/risk assessment of medicinal products. In addition, the pertinent role of quality assurance and the respective methods to be developed for every subject as well as the legal aspects based on law and adjudgement will be addressed in order to support the right decision making.

Well-known speakers in pharmacovigilance from authorities, pharma industry, law office and service provider will discuss together openly supporting appropriate solutions if applicable.

The Scientific Board, **Dr. Leonardo Ebeling**, *Managing Director* at Dr. Ebeling & Assoc. GmbH will share best practices, results and experiences in this field.

Who should attend?

The seminar is ideally suited for employees of small-, middle- and large-sized companies in the pharmaceutical sector especially concerned with the implementation and/or maintenance of pharmacovigilance (PV) systems, with its critical PV processes and quality system. Participants may come from various departments involved in fulfilling legal PV requirements.

Official language: German (slides of presentations will be in English)

SPONSORED BY:



MEDIA PARTNER:



PHVday

PHARMACOVIGILANCE 2015

Hot Topics in Pharmacovigilance

AGENDA

SPONSORED BY:



MEDIA PARTNER:



- 09:00 - 10:00 **Registration and welcome coffee**
- 10:00 - 10:05 **Welcome from the Chairman**
Dr. Leonardo Ebeling, Managing Director, Dr. Ebeling & Assoc. GmbH
- 10:05 - 10:35 *Dr. Aleksei Babich, Medical Advisor, Lead Expert Signal Management, Grünenthal GmbH*
Statistical Signal Detection/Data Mining in the routine Signal Detection-Efficiency perspective
- 10:35 - 11:05 *Dr. Heinz Weidenthaler, Director Drug Safety & Pharmacovigilance, QPPV, Bavarian Nordic GmbH*
Risk Management Plans – The roles of the MAH and of the Competent Authority
- 11:05 - 11:35 **Coffee Break**
- 11:35 - 12:05 *Dr. Leonardo Ebeling, Managing Director, Dr. Ebeling & Assoc GmbH*
Important Risks in the EU PV-Legislation and Guidance: Best Practices to allow optimised patient safety?
- 12:05 - 12:50 *Dr. Matthias Runge, Sander & Krüger Rechtsanwälte PartGmbH*
Relevant legal pitfalls in PV:
- Local QPPV vs EU-QPPV vs Global QPPV
- RMP – Ownership and Liability Risks of MAH and Competent Authority
- Risk Labelling: Legal implications if a similar product has a different risk label: in the own portfolio; in a national/EU country; in ROW
- 12:50 - 13:10 **Panel Discussion on “Hot Topics in Pharmacovigilance”**
- 13:10 - 13:55 **Networking Lunch**
- 13:55 - 14:25 *Dr. Kerstin Geldmeyer-Hilt, Quality Management, Dr. Ebeling & Assoc GmbH*
Compliance with the EU legislation and EU guidance: The role of Quality Management in PV and Drug Safety
- 14:25 - 14:55 *Dr. Uwe Schulz, Head of Pharmacovigilance and Regulatory Affairs, Recordati Pharma GmbH*
Internal and external auditing of pharmacovigilance systems
- 14:55 - 15:25 **Coffee Break**
- 15:25 - 15:55 *Dr. Marc Zittartz, Chief Quality Officer, pharmaSOL*
The rise of the Medical Device/Pharmaceutical Product combination and how it affects traditional Pharmacovigilance
- 15:55 - 16:25 *Dr. Axel Thiele, Senior Expert Pharmacovigilance, Bonn*
The European Referral Procedure - Update:
-Urgent Union Procedure/Standard Procedure
-The role of PRAC
-Timelines for implementation
-Problems in national implementation
-Influence of the variation regulation
- 16:25 - 16:35 **Conclusions**

PHVday

PHARMACOVIGILANCE 2015

SPONSORED BY:



MEDIA PARTNER:



Registration

In order to attend the *German Pharmacovigilance Day* conference, you can send the filled registration form, for each attendee, via email: info@easy-b.it or via fax: **+39.035.4501262** and pay by bank transfer

OR

you can directly register online and pay by credit card, clicking on:
<http://events.lisacademy.it/conferences>

Registration fee

€ 490,00 **Early Bird fee extended until 22th May 2015**

€ 610,00 ordinary fee (after 22th May 2015)

€ 440,00 Patronage members fee

€ 360,00 for Universities, Hospitals, public administration and Freelancer

*The **fee includes**: seat at the conference, copy of presentations of Speakers who allow the distribution, informative literature for the day, networking lunch, coffee breaks, organisational office assistance, certificate of attendance.*

Methods of payment

If you pay by bank transfer, please attach proof of payment to the registration form.
Bank transfer payable to:

EasyB S.r.l.

Via Roma, 20 - 24022 Alzano Lombardo (BERGAMO)

VAT number: IT03633040161

Banca Popolare di Vicenza - Filiale di Nese

IBAN: IT36 B057 2853 2508 2657 0697 999

SWIFT Code: BPVIIT21826

If you pay online (by credit card), you need to register clicking on:

<http://events.lisacademy.it/conferences>

Invoice will be sent following receipt of payment as proof of received payment

How to reach InterCity Hotel Frankfurt Airport - Frankfurt am Main

For further information please visit:

www.pharmacovigilanceday.com or

<http://en.intercityhotel.com/Frankfurt/InterCityHotel-Frankfurt-Airport>

Terms of payment

The registration fee must be paid at the time of registration. Confirmation of event admission will be given on receipt of payment. EasyB reserves the right to refuse late registrations or additional registrations above the maximum accepted number of participants or registrations of roles that are not included in the target of the event.

Cancellation

Please note that refunds (70% refund of the registration fee) will only be given if cancellation is received at least one week before the event date. Cancellations will only be valid if made in writing (by email).

Transfer of registrations (or name changes) are allowed and should be made in writing within 7 days prior to the event. EasyB reserves the right to postpone or cancel an event, to change the location of an event or to alter the advertised speakers for an event. EasyB is not responsible for any loss or damage as a result of substitution, alteration, postponement or cancellation of an event due to causes beyond its control including without limitation, acts of God, natural disasters, sabotage, accident, trade of industrial disputes, terrorism, or hostilities.

Information collection and use

Participants information is collected and utilised by EasyB S.r.l. and sponsor companies in accordance with Italian Legislative Decree 196/2003. Data collected will be used and communicated to third parties for the purposes of event organisation and may be used to communicate future similar initiatives. Participants may at any time verify the accuracy of the information and request changes or deletion.

PHVday

PHARMACOVIGILANCE 2015

IN ORDER TO ATTEND THE GERMAN PV DAY, PLEASE COMPLETE THE REGISTRATION FORM FOR EACH ATTENDEE AND SEND IT VIA FAX: +39.035.4501262 OR VIA EMAIL: info@easy-b.it

- € 490,00 Early Bird fee extended until 22th May 2015
- € 610,00 Ordinary fee (after 22th May 2015)
- € 440,00 Patronage members fee
- € 360,00 for Academy, Public Administration, Freelance
(please specify.....)

The fee includes: seat at the conference, copy of presentations Speakers who allow the distribution, informative literature for the day, networking lunch, coffee breaks, organisational office assistance, certificate of attendance.

Method of payment

The full amount must be paid on registration to EasyB s.r.l by bank transfer.
If paying by bank transfer please attach proof of payment to the registration form. Bank transfer payable to:

EasyB S.r.l.
Via Roma, 20 - 24022 Alzano Lombardo (BG)
VAT: IT03633040161
Banca Popolare di Vicenza - Filiale di Nese
IBAN: IT36 B057 2853 2508 2657 0697 999
SWIFT Code: BPVIT21826

For any additional information, please contact:

info@easy-b.it Phone: +39.035.515684 Fax: +39.035.4501262

Name		Surname	
Company		Job Title	
Address			
City		Post Code	
Phone number		Fax	
E-mail			
Special dietary requests			

INVOICING DETAILS

Company name			
Address			
Mail address (if different)			
City		Post Code	
VAT number			

Terms of payment

The registration fee must be paid at the time of registration. Confirmation of event admission will be given on receipt of payment. EasyB reserves the right to refuse late registrations or additional registrations above the maximum accepted number of participants or registrations of roles that are not included in the target of the event.

Cancellation

Please note that refunds (70% refund of the registration fee) will only be given if cancellation is received at least one week before the event date. Cancellations will only be valid if made in writing (by email). Transfer of registrations (or name changes) are allowed and should be made in writing within 7 days prior to the event. EasyB reserves the right to postpone or cancel an event, to change the location of an event or to alter the advertised speakers for an event. EasyB is not responsible for any loss or damage as a result of substitution, alteration, postponement or cancellation of an event due to causes beyond its control including without limitation, acts of God, natural disasters, sabotage, accident, trade of industrial disputes, terrorism, or hostilities.

Information collection and use

Participants information is collected and utilised by EasyB S.r.l. and sponsor companies in accordance with Italian Legislative Decree 196/2003. Data collected will be used and communicated to third parties for the purposes of event organisation and may be used to communicate future similar initiatives. Participants may at any time verify the accuracy of the information and request changes or deletion.



Date

Signature.....