

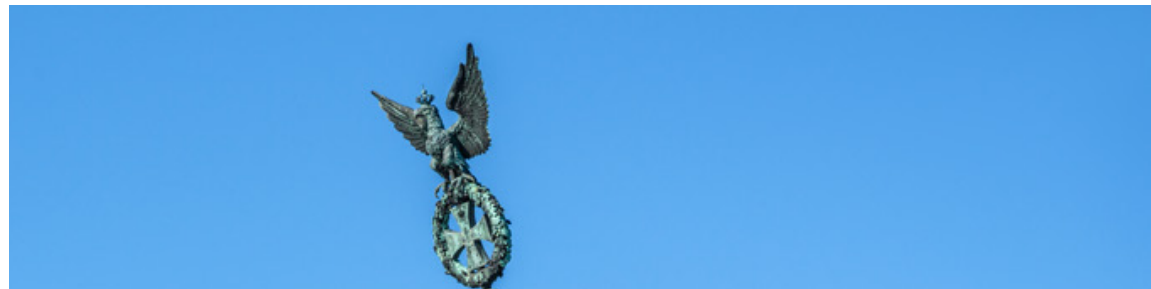
PHVday

PHARMACOVIGILANCE 2016

German Pharmacovigilance Day 2016

EU-Challenges in Pharmacovigilance/Vigilance:
"Hot Topics in 2016"

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Berlin, Germany

Crowne Plaza Berlin-Potsdamer Platz
Hallesche Straße 10, 10963 - Berlin

Thursday, April 14th 2016

EU-Challenges in Pharmacovigilance/Vigilance: “Hot Topics in 2016”

2016 will be a very challenging year for all people dealing with safety of drugs, biologics and devices.

Further to the EMA-projects we have to consider that compliance with regulatory guidance becomes much more complicated and pragmatic approaches are key.

The PhV Day 2016 will provide solutions on how to handle with medication errors, MLM, E2B updates, inspection readiness, and risk management. The key for every PV-system is the adequate interaction between Regulatory Affairs and Pharmacovigilance. Further perspectives of product safety will be addressed for NCEs, Biologics and Medical Devices and the responsibilities cleared for the MAH and legal functions like EU-QPPV and local PV contact persons.

Scientific Board:

Dr. Leonardo Ebeling, *Managing Director* at Dr. Ebeling & Assoc. GmbH

Who should attend the conference?

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/Vigilance Systems, with its critical processes and quality system. Participants may come from various departments involved in fulfilling Pharmacovigilance/Vigilance requirements as legal Medical Affairs and Regulatory Affairs.

Official language: German

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Agenda

- 09:00 - 10:00 **Registration and welcome coffee**
- 10:00** **Start of the conference**
- 10:00 - 10:05 **Welcome from the Chairman**
Dr. Leonardo Ebeling - Managing Director, Dr. Ebeling & Assoc. GmbH
- 10:05 - 10:35 **Medication Error: Impact on the Pharmacovigilance-System**
Dr. Uwe Schulz - Head of Pharmacovigilance and Regulatory Affairs, Recordati Pharma GmbH
- 10:35 - 11:05 **MLM-Compliance: How to use MLM from EMA?**
Dr. Leonardo Ebeling - Managing Director, Dr. Ebeling & Assoc. GmbH
- 11:05 - 11:35 **Coffee break**
- 11:35 - 12:05 **8 ways to say I don't know – The impact of null Flavors in E2B (R3)**
Dr. Marc Zittartz - Chief Quality Officer, pharmaSOL
- 12:05 - 12:35 **Pharmacovigilance-Inspections in the EU: Transparency, Short-Comings, Harmonisation**
Dr. Axel Thiele - Senior Expert Pharmacovigilance, Bonn
- 12:35 - 13:20 **Networking Lunch**
- 13:20 - 13:50 **Risk Management Strategy – Differences and Similarities between EU RMP and US REMS**
Dr. Heinz Weidenthaler - Director Pharmacovigilance, QPPV, Bavarian Nordic GmbH
- 13:50 - 14:20 **PV-Interactions with Distributors, Licensors or external MAHs - How to deal with Senior/Junior Partners, Implications for SDEAs, Regulatory Interdependencies**
Martin Dornseiff - Head of Medical Affairs, InfectoPharm Arzneimittel und Consilium GmbH
- 14:20 - 14:50 **Some similarities and differences of the PV-Activities regarding NCEs and Biologics**
Dr. Ute Höffner - Sr Medical Director Safety and Benefit-Risk Management, Biogen Idec Ltd.
- 14:50 - 15:20 **Coffee break**
- 15:20 - 15:50 **Pharmacovigilance from a legal perspective: Liabilities of MAH, QPPV and Stufenplanbeauftragter**
Dr. Matthias Runge - Sander & Krüger Rechtsanwälte PartGmbH
- 15:50 - 16:20 **Vigilance for Medical Devices**
Dr. Nadine Epp - Quality Management, Dr. Ebeling & Assoc. GmbH
- 16:20 - 16:30 **Conclusions**

How to reach the Crowne Plaza Berlin-Potsdamer Platz

For further information, please visit the conference website:
<http://germanpharmacovigilanceday2016.eventify.it/>

In order to attend the German PHV Day, please complete the registration form for each attendee and send it via e-mail: events@phvday.com or via fax: **+39.035.4501262**

Please note that you can directly register on the website <http://germanpharmacovigilanceday2016.eventify.it/orders/new> and you can choose to pay by credit card or by bank transfer.

€ 515,00 Early Bird fee, extended until March, 29th 2016

€ 640,00 ordinary fee (after 29th March 2016)

€ 412,00 coupon code fee via Life Science Academy (valid until March 18th, 2016) (please specify the code)

€ 460,00 Patronage members fee (association)

€ 370,00 for Academy, Public Administration and Freelancer (please specify)

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

For any additional information, please contact:

Stefania Sarga
events@phvday.com
Phone: +39(0)35.515684 - Fax: +39(0)35.4501262

Methods 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.

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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.

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