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PHVday

PHARMACOVIGILANCE 2017

**PV and Vigilance duties and challenges in the practice:
What are and might be the typical problems and how to (re)act?**



Frankfurt am Main, Germany

Thursday, May 4th 2017

Lufthansa Flight Training Frankfurt

Airportring, Gate 24, Buildings 391 and 392 - Frankfurt am Main

Event Managed by



PV and Vigilance duties and challenges in the practice: What are and might be the typical problems and how to (re)act?

Pharmacovigilance (PV) is not only an obligation for all Marketing Authorisation Holders (MAHs) and Sponsors of clinical trials but also an important requirement in order to protect public health. Current changes within the legislation of post-authorisation and clinical trials as well as the upcoming implementation of the EudraVigilance (EV) system will necessitate an adjustment of the existing internal systems of the MAHs. The 4th German Pharmacovigilance Day aims to provide information about e.g. EU wide standardisation and simplified reporting via the new ICH-E2B (R3) format, new data elements and additional requirements. Additionally, it will focus on the MAHs' access to EudraVigilance with regard to the EV Database Warehouse and Analysis System (EVDAS) and data output in form of an electronic Reaction Monitoring Report (eRMR). The mentioned changes will have considerable impact on the overall PV system and need to be appropriately addressed within the PSMF (Pharmacovigilance System Master File).

During the day, the discussion will be also focused on:

- planned timelines of implementation and available trainings
- new features of the ICH-E2B (R3) format
- EVDAS access and main principles (signal detection and data analysis)
- eRMR functionalities
- different levels of access to EudraVigilance and
- current knowledge about the best methods of statistical signal detection
- and much more

Leonardo Ebeling, Managing Director at Ebeling & Assoc. GmbH, as Scientific Board, will lead a panel of experts to share best practices, knowledge and experience in this field.

Official language: German

Who should attend?

This one-day conference is designed to benefit functional/technical professionals working in the pharmaceutical and health care system dealing with the Pharmacovigilance system, such as:

- Pharmacovigilance dept.
- Clinical operation dept.
- Statistic dept.
- Medical Affairs dept.
- Regulatory Affairs dept.
- Quality & Compliance dept.

in pharmaceutical and Biotech companies, Clinical Research Organizations (CROs) and public health centers.

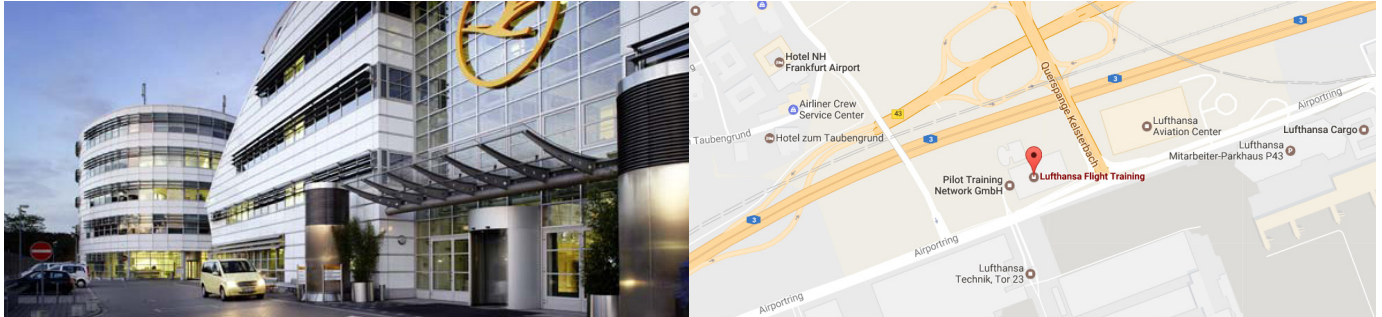
PV and Vigilance duties and challenges in the practice: What are and might be the typical problems and how to (re)act?

Agenda

- 09:00 – 09:45 **Registration and welcome coffee**
- 09:45 – 09:50 **Welcome from the Chairman**
Dr. Leonardo Ebeling, *Managing Director* at Dr. Ebeling & Assoc. GmbH
- SPECIALS**
- 09:50 – 10:20 **Dr. Heinz Weidenthaler**, *Director Pharmacovigilance, QPPV* at Bavarian Nordic GmbH
Pharmacovigilance in vaccines – Differences and similarities with respect to usual standards
- 10:20 – 10:50 **Dr. Lisa Juris**, *Pharmacovigilance/Vigilance Manage* at Dr. Ebeling & Assoc. GmbH
Medical Devices – The challenges of the new European Regulation – How to adapt and when?
- 10:50 – 11:20 **Dr. Axel Thiele**, *Senior Expert Pharmacovigilance, Bonn*
Social Media and PV – Dos and Don'ts – What is required and what has to be considered?
- 11:20 – 11:50 **Coffee Break**
- 11:50 – 12:20 **Dr. Matthias Runge**, *Sander & Krüger Rechtsanwälte PartGmbH*
Referrals – The role of the EU-QPPV
- 12:20 – 12:50 **Dr. Joyce De Langen**, *Senior Solution Manager Pharmacovigilance* at Elsevier
Pharmacovigilance and the role of literature: Challenges and solutions
- 12:50 – 13:50 **Networking Lunch**
- EUDRAVIGILANCE**
- 13:50 – 14:20 **Dr. Marc Zittartz**, *Chief Quality Officer* at pharmasol
E2B (R2) vs. E2B (R3) – Differences and challenges
- 14:20 – 14:50 **Rosa Meixner**, *Global Head of PV Agreements & Compliance* at Sandoz International GmbH
PSMF – What to consider in practice?
- 14:50 – 15:20 **Dr. Leonardo Ebeling**, *Managing Director* at Dr. Ebeling & Assoc. GmbH
**November 2017 – EudraVigilance Change Management:
Nightmare, L'art pour l'art or (appropriate) World Standard of PV?
EVDAS – How to manage and to integrate into the own Signal Evaluations?
Progress in MLM: Additional burden or facilitation?**
- 15:20 – 15:50 **Coffee Break**
- STUDIES**
- 15:50 – 16:20 **Martin Dornseiff**, *Head of Medical Affairs and EU-QPPV* at InfectoPharm Arzneimittel und Consilium GmbH
PV challenges in a large multinational science-driven non-interventional study
- 16:20 – 16:50 **Bettina Rillmann**, *Scientific Affairs Director, Late Phase Services* at Pharmaceutical Research Associates GmbH
PASS to evaluate the effectiveness of RMMs
- 16:50 – 17:00 **Conclusions**

How to reach the conference venue

Venue | **Lufthansa Flight Training Frankfurt** | Airportring, Gate 24, Buildings 391 and 392 - Frankfurt am Main, Germany



The Lufthansa Flight Training Center Frankfurt is located at Frankfurt Airport, easily accessible by road (highway) or rail (two train stations directly at the airport).

Directions by car

Take either of the A3, A5 or B43 highways and follow the signs for "Frankfurt Flughafen" and then for "Tor 21-31".

Directions by train and bus

Regional trains (S8 or S9)

From the Regional Railway Station: Either take a taxi, or proceed to the bus stop 25 or 11-13 and take the complimentary shuttle bus "WEST (Tor 25/27)".

National/International trains (InterCity (IC), Intercity-Express (ICE))

From the International Railway Station: Proceed to the Regional Railway Station, then follow the directions above.

Directions by plane

From Terminal 1: Either take a taxi, or proceed to the bus stop 25 or 11-13 at Arrival Hall A and take the complimentary shuttle bus "WEST (Tor 25/27)".

From Terminal 2: Take the Sky Line to Terminal 1. Then either take a taxi, or proceed to the bus stop 25 or 11-13 and take the complimentary shuttle bus "WEST (Tor 25/27)".

[For further information, please download the Pocket Guide](#)

For further information please visit the conference [website](#) or contact the organization offices:

Stefania Sarga Phone: +39 (0)35.4123594 | Mail: stefania.sarga@LSacademy.it

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[Download the Events Summary 2017](#)

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- **Online:** please register here <https://germanpharmacovigilanceday2017.eventify.it/orders/new>
In this case, you can choose to pay by credit card or by bank transfer.
- **By email or fax:** please fill the registration form below for each attendee and send it by email:
stefania.sarga@LSAcademy.it or by fax: **+39(0)35.4501262** In this case, you can pay by bank transfer.

■ € 595,00 Early Bird fee until 3rd April 2017

■ € 710,00 Ordinary fee (after 3rd April 2017)

■ € 540,00 Patronage members fee (Association _____)

■ € 390,00 for Academy, Public Administration, Freelance (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, coffee break, organisational office assistance, certificate of attendance.

For any additional information, please contact:

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The full amount must be paid on registration to EasyB S.r.l. by bank transfer. If you pay by bank transfer, please attach proof of payment to the registration form.

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