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## German Pharmacovigilance Day

Wednesday, **June 20<sup>th</sup>**, 2018

# THE BIG CHANGES IN THE EUROPEAN **PHARMACOVIGILANCE** **AND VIGILANCE**

📍 | Frankfurt am Main, Germany

InterCity Hotel Frankfurt Airport

Am Luftbrückendenkmal 1 - Cargo City Süd

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## THE BIG CHANGES IN THE EUROPEAN PHARMACOVIGILANCE AND VIGILANCE

### How to deal with the opportunities and pitfalls of the new EMA projects and with the MDR

The German Pharmacovigilance Day 2018 will present how experts handle the new features of the EudraVigilance-System including EVDAS. What are the best strategies to overcome the huge workload and how to justify the newly defined processes in the own Pharmacovigilance- and Vigilance-System? Answers will be given in the perspective also of SMEs. However, also legal aspects and the view of Pharmacovigilance-Inspectors of Notified Bodies will be addressed.

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

- PSURs for Medical Devices
- Clinical Evaluation Plans and Clinical Expert Reports for Medical Devices
- ADR-reporting to Non-EU
- EVDAS access and main principles (signal detection and data analysis)
- eRMR functionalities
- different levels of access to EudraVigilance
- and much more

#### Scientific Board



**Dr. Leonardo Ebeling**

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

#### 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:

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

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

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# THE BIG CHANGES IN THE EUROPEAN PHARMACOVIGILANCE AND VIGILANCE

- 09:15 - 09:45 **Registration and welcome coffee**
- 09:45 - 09:50 **Welcome from the Chairman**  
Dr. Leonardo Ebeling - *Managing Director* at Dr. Ebeling & Assoc. GmbH
- 09:50 - 10:05 **Dr. Leonardo Ebeling - Managing Director at Dr. Ebeling & Assoc. GmbH**  
**Overview on EMA/EU Hot Topics and Policies**
- 10:05 - 10:35 **Rosa Meixner - Global Head of PV Agreements & Compliance at Sandoz International GmbH**  
**Safety Data Exchange with License Partners: Scope, Issues and Solutions also in the light of the new EV Policies**
- 10:35 - 11:05 **Dr. Marc Zittartz - Chief Quality Officer at pharmaSOL**  
**EudraVigilance - How to survive the ICSR Download Avalanche**
- 11:05 - 11:35 **Coffee break**
- 11:35 - 12:05 **Dr. Heinz Weidenthaler - Director Pharmacovigilance, QPPV at Bavarian Nordic GmbH**  
**Aligning Signal and Risk Management from a Small Company's Perspective**
- 12:05 - 12:35 **Dr. Nadine Epp - Quality Management, Dr. Ebeling & Assoc. GmbH**  
**The EViSiMa® - project - Signal Management for SMEs**
- 12:35 - 13:05 **Herbert Wartensleben - Rechtsanwalt at Anwaltskanzlei Wartensleben**  
**The significance of EVDAS for the Signal Management from a legal Perspective - Risks for PU/MAH and StPB/EU-QPPV**
- 13:05 - 14:05 **Networking lunch**
- 14:05 - 14:35 **Dr. Bianca Scholz - Consulting & Project Management at ScholzPharma GmbH**  
**PV-Inspections Readiness: What has to be considered and how with regard to the GVP-updates?**
- 14:35 - 15:05 **Dr. Axel Thiele - Senior Expert Pharmacovigilance, Bonn**  
**What will PV-Inspectors address and how (and what not wrt) the EV enhanced functionalities 2018?**
- 15:05 - 15:35 **Coffee break**
- 15:35 - 16:05 **Jessica Trotzki - Account Manager Life Sciences at Elsevier**  
**Literature Management for Pharmacovigilance**
- 16:05 - 16:20 **Dr. Leonardo Ebeling - Managing Director at Dr. Ebeling & Assoc. GmbH**  
**The new MDR - How to prepare for?**
- 16:20 - 16:50 **Dr. Sabrina Lehmann - Pharmacovigilance/Vigilance Manager at Dr. Ebeling & Assoc. GmbH**  
**Equivalent versus own (clinical) data - The Clinical Evaluation Report according to MEDDEV 2.7/1 rev. 4**
- 16:50 - 17:00 **Conclusions**

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# HOW TO REACH THE CONFERENCE VENUE

## InterCity Hotel Frankfurt Airport

Am Luftbrückendenkmal 1 - Cargo City Süd - Frankfurt am Main, Germany



### Arriving by airplane

**Airport: Frankfurt Rhein-Main Airport/FRA** The hotel offer guests a shuttle bus service from and to the passenger terminals 1 + 2 (fee required). Daily from the hotel to the terminals 1 + 2 every 30 minutes from 4:45 h onwards. Last trip from terminal 1 to the hotel is at 0:30 h. The bus ride takes approximately 8 minutes per route.

**Terminal 1** Exit B5 on the arrival level    **Terminal 2** Exit D/E 6

### Arriving by train

**Train station: Frankfurt/Main Airport** At the airport please take the shuttle bus from terminal 1 stop B5 or from terminal 2 stop D/E.

### Arriving by car

**Navigation device** | Am Luftbrückendenkmal 1/Cargo City Süd 60549 Frankfurt

**Via the GPS coordinates** | Longitude: 8.584 Latitute: 50.027

*Please be aware that in many navigation systems this street name still does not exist.*

**Via A5 (Basle, Frankfurt/Main)** | Take the exit 23 "Zeppelinheim, CargoCity Süd"

**Car park** | Public car park is available next to the hotel.



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### For further information

Please visit [the conference website](#) or contact the organisational offices:

**Stefania Sarga** Phone: +39 (0)35.4123594 | [stefania.sarga@LSacademy.it](mailto:stefania.sarga@LSacademy.it)

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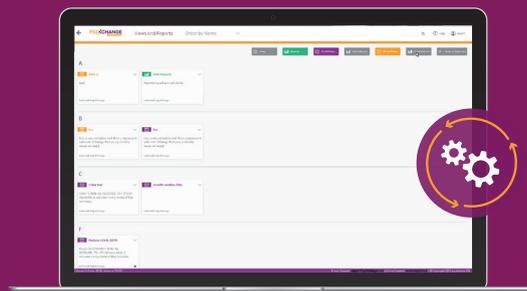


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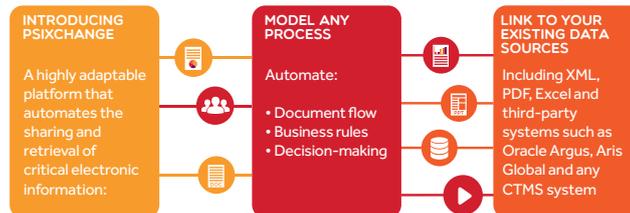
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# Two ways to register

## • Online

please register here

<https://germanpharmacovigilanceday2018.lscademyevents.it/orders/new>

In this case, you can choose to pay by credit card or by bank transfer

## • By email o fax

please fill the registration form below for each attendee and send it

by **email** : [stefania.sarga@LSacademy.it](mailto:stefania.sarga@LSacademy.it) or by **fax** : +39(0)35.4501262

In this case, you can pay by bank transfer.

- € 655,00 Early Bird fee extended until June 8th, 2018
- € 765,00 Ordinary fee (after June 8th, 2018)
- € 570,00 Patronage members fee (Association \_\_\_\_\_ )
- € 430,00 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:

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

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I wish that my data (name, surname, job position and company) are inserted in the list of attendees distributed the day of the event  Yes  No

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**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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Date \_\_\_\_\_ Signature \_\_\_\_\_