

Event managed by



PhVday
PHARMACOVIGILANCE 2018

German Pharmacovigilance Day

Wednesday, **June 20th**, 2018

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

📍 | Frankfurt am Main, Germany

InterCity Hotel Frankfurt Airport

Am Luftbrückendenkmal 1 - Cargo City Süd

Sponsored by:



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.

Event managed by



LIFE SCIENCE
ACADEMY

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**

Event managed by



LIFE SCIENCE
ACADEMY

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 Latitude: 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.





SPONSORSHIP OPPORTUNITIES



Sponsor the event and take the chance to network with all attendees!

Exclusive benefits and high impact branding before, during and after the conference.

Download the **Events Summary 2018**



For further information

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

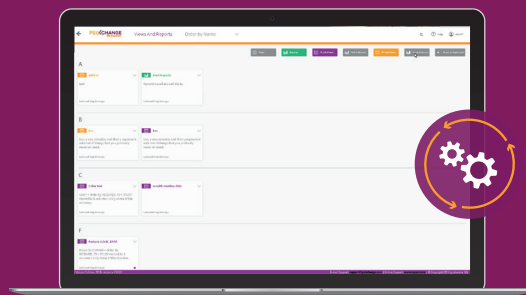
Stefania Sarga Phone: +39 (0)35.4123594 | stefania.sarga@LSacademy.it

Event managed by



COMPLETE CONFIDENCE IN FULFILLING YOUR REPORTING OBLIGATIONS

A controlled document distribution process, in which getting the right information to the intended recipients within a desired, or required, timeframe and being able to track delivery status and confirm receipt, is a challenge for regulated industries.



DOCUMENT DISTRIBUTION

A PROCESS THAT IS TYPICALLY....

MANUAL



EXPENSIVE



TIME
CONSUMING



COMPLEX



And from a compliance perspective, it's:

Difficult to track progress
with no clear audit trail

PSIXCHANGE OFFERS A BETTER WAY

INTRODUCING PSIXCHANGE

A highly adaptable platform that automates the sharing and retrieval of critical electronic information:

MODEL ANY PROCESS

Automate:

- Document flow
- Business rules
- Decision-making

LINK TO YOUR EXISTING DATA SOURCES

Including XML, PDF, Excel and third-party systems such as Oracle Argus, Aris Global and any CTMS system

- COMPLETE AUTOMATION
- DISTRIBUTION ON A PRODUCT LEVEL
- ACCEPTED BY SITES, ECS, RAS
- DETAILED COMPLIANCE DASHBOARD
- WORKS WITH ANY SAFETYDATABASE

WWW.PSIXCHANGE.COM

TO MAKE AN ENQUIRY OR SCHEDULE A DEMO E-MAIL TIM.BILLINGTON@PHARMASOL.DE

Mediconomics – expertise since 1999



Clinical Research

Regulatory Affairs

Medical Devices

Medical Writing

Pharmacovigilance

Product Development

Data Management

Your specialist in Pharmacovigilance Service Provision

Mediconomics offers a full catalogue of readily accessible pharmacovigilance services which can be expertly tailored to our clients' exact specifications, allowing them to choose the level of support they require.

Benefit from our experience in:

- Compliance with EU conform electronic reporting (XEVPRM, ICSR)
- Implementation of PV systems
- Compilation of risk management plans (RMPs)
- Periodic safety update reports (PSURs)
- Evaluation of the current PV status
- Alarm plans
- Reporting
- Literature research
- Training and Internal audits

Give us a call: +49 (0) 511 560 998-0,
e-mail: info@mediconomics.com,
or visit us at www.mediconomics.com

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 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.

Payment by bank transfer

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.

Bank transfer payable to:

EasyB S.r.l.

Via Roma, 20 - 24022 Alzano Lombardo (Bergamo)

VAT: IT03633040161

BANCO BMP – Filiale di Carobbio degli Angeli

IBAN: **IT81 F 05034 53960 000000003450**

SWIFT Code: **BAPPIT21AY5**

For any additional information, please contact:

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

Surname _____ Name _____
Company _____ Job title _____
Address _____
City _____ Post code _____
Phone _____ Fax. _____
E-mail _____
Special Dietary Requests _____

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

Invoicing details

Company name _____
Address _____
Mail address (If different) _____ Post code _____
City _____
VAT number _____

Terms & Conditions

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 In accordance with the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016, we inform you that EasyB S.r.l. (with headquarters in Via Roma 20, Alzano Lombardo, Bergamo, Italy, VAT number IT03633040161) will use your personal data voluntarily provided by you only with the consent and in compliance with the principles dictated by the European Regulations on the protection of personal data for sending newsletters, for marketing purposes (sending advertising material, market research and commercial communication) and for communication purposes to third parties (companies that sponsor the event, scientific board, speakers), also for marketing goals. You can read the complete information, including your rights and the procedures for the exercise of the same, [following this link](#).

Event managed by



LIFE SCIENCE
ACADEMY

Date _____ Signature _____