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PhVday
PHARMACOVIGILANCE 2019

German Pharmacovigilance Day

Thursday, June 6th, 2019

SIGNAL MANAGEMENT AND EVDAS/EUDAMED – **WHAT, WHEN, WHY AND HOW?**



Frankfurt am Main

Zeppelin-Museum Zeppelinheim

Kapitän-Lehmann-Str. 2 - 63263 Neu-Isenburg
(Zeppelinheim) - Frankfurt am Main, Germany

Sponsor



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SIGNAL MANAGEMENT AND EVDAS/EUDAMED – WHAT, WHEN, WHY AND HOW?

This conference will deal with the legal, regulatory and scientific requirements of Signal Management including updates of Safety Relevant Information with and without respect to EVDAS. Different approaches to fulfil the obligations and to substantially increase patient's safety will be presented and discussed. Associated topics like SDEAs and GDPR in Signal Management are also covered.

Chairman



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.
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SIGNAL MANAGEMENT AND EVDAS/EUDAMED – WHAT, WHEN, WHY AND HOW?

- 09:00 - 09:30 **Registration and welcome coffee**
- 09:30 - 09:35 **Welcome from the Chairman: Why Signal Management is key today?**
Dr. Leonardo Ebeling - *Managing Director* at Dr. Ebeling & Assoc. GmbH
- 09:35 - 10:10 **What are the fundamentals of Signal Management for Medical Devices with and without EUDAMED?**
Dr. Jasmin Lindner - *Medical Science and Affairs / Vigilance and Pharmacovigilance* at Dr. Ebeling & Assoc. GmbH
- 10:10 - 10:55 **What are the fundamentals of Signal Management for Medicinal Products with and without EVDAS?**
Dr. Andrej Miotk - *Manager Drug Safety and Product Labelling* at InfectoPharm Arzneimittel und Consilium GmbH
- 10:55 - 11:25 **Coffee break**
- 11:25 - 12:00 **Do MAHs/PUs have to monitor EVDAS in order to detect signals and update the product information as soon as possible – independent from the pilot phase?**
Herbert Wartensleben - *Rechtsanwalt* at Anwaltskanzlei Wartensleben
- 12:00 - 12:35 **The EV-case reports on ADRs and Signal management:
Can/Should we avoid to download NCA- or 'other MAH'-cases – how and when?**
Dr. Uwe Schulz - *Head of Pharmacovigilance and Regulatory Affairs* at Recordati Pharma GmbH
- 12:35 - 13:35 **Networking Lunch**
- 13:35 - 14:05 **How PV inspectors will address the Signal Management compliance?**
Dr. Axel Thiele - *Senior Expert Pharmacovigilance* at Bonn
- 14:05 - 14:40 **The EViSiMa®-Project – How to survive EVDAS with generics and WEU drugs?**
Dr. Nadine Epp - *Quality Management Representative* at Dr. Ebeling & Assoc. GmbH
- 14:40 - 15:10 **Coffee break**
- 15:10 - 15:40 **How to deal with safety-related actions as a consequence of the Signal Management by the EU-QPPV and the GPO (Stufenplanbeauftragter) – Who is responsible for what?**
Dr. Enno Burk - *Rechtsanwalt* at Gleiss Lutz Hootz Hirsch PartmbB Rechtsanwälte
- 15:40 - 16:10 **The Data Protection rules in the EU with respect to Signal assessments - Does the system allow for appropriate investigations?**
Dr. Marc Zittartz - *Chief Quality Officer* at pharmaSOL
- 16:10 - 16:40 **AI and Machine Learning literature monitoring**
Mark Drinkwater - *Co-founder of Pi2 Solutions* at ProQuest
** this presentation will be in english*
- 16:40 - 16:45 **Conclusions**
Dr. Leonardo Ebeling - *Managing Director* at Dr. Ebeling & Assoc. GmbH

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HOW TO REACH THE CONFERENCE VENUE

Zeppelin-Museum Zeppelinheim

Kapitän-Lehmann-Str. 2 - 63263 Neu-Isenburg
(Zeppelinheim) - Frankfurt am Main, Germany



The venue of the conference is located just:

- 20 minutes from Frankfurt Central Station by “S-Bahn” line 7
- 7 minutes from Frankfurt Airport (FRA) by Taxi

For all participants the chance to take a tour of the museum.

The Zeppelin Museum Zeppelinheim is a tribute to the iconic airship “LZ 10”. It is located near Frankfurt Airport (FRA), easily accessible by road or by public transport. The building concept is based on the design of Zeppelin airship “LZ 10”. The round roof-structure, which corresponds to a quarter section of the Zeppelin, impressively gives an idea of the size of the “giants of the sky”.

Directions

by car :

Driving on the Autobahn A5 take exit 23 “Zeppelinheim” and follow the direction Neu-Isenburg / Zeppelinheim / Dreieich. At the first traffic light turn left into the street “Flughafenstraße”. Follow the signs “Zeppelinmuseum”. Driving on the Autobahn A3 take exit 51 “Walldorf” and drive through the roundabout/rotary intersection, taking the national road B44, following direction Groß-Gerau / Walldorf / Neu-Isenburg . Then take the second exit to Zeppelinheim. Follow the street until it ends at another road. Turn right and follow the signs “Zeppelinmuseum”.

by train and bus:

From Neu-Isenburg via bus line OF 51 to stop “Ludwig-Dürr-Straße”. Use the pedestrian walk way near to the bus stop heading to the street “Kapitän-Lehmann-Straße” and you will see the museum on the left side, easily recognizable by the impressive round roof structure. From Frankfurt or Groß-Gerau by “S-Bahn” linie S 7 to Zeppelinheim. Walk on the street “Flughafenstraße” in the direction of the town center. turn left into “Mathilde-Rösch-Straße” and afterwards turn right into “Kapitän-Lehmann-Straße”. Just follow the street for approx. 400m. The museum will appear on the right side, easily recognizable by the impressive round roof structure as an extension to the community center “Bürgerhaus Zeppelinheim”.

by plane The Frankfurt Airport (FRA) is:

- just 7 minutes by Taxi
- 30 minutes by public transport



For further information

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

Federica Bertoli Phone: +39 (0)35.4123594 | federica.bertoli@lsacademy.com

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Two ways to register

• Online

please register here

<https://germanpharmacovigilanceday2019.lsacademyevents.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: federica.bertoli@lsacademy.com** or by **fax: +39(0)35.4501262**

In this case, you can pay by bank transfer.

■ **€ 655,00 Early Bird fee extended until May 22nd, 2019**

■ **€ 765,00 Ordinary fee** (after May 22nd, 2019)

■ **€ 570,00 Patronage members fee** (Association _____)

■ **€ 430,00 Academy, Public Administration, Freelance**
(please, specify _____)

■ **€ 550,00 Past edition delegates** (until May 09, 2019)

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.

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For any additional information, please contact: Federica Bertoli | federica.bertoli@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

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Terms & Conditions

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Date _____ Signature _____