PHVday
PharmacoVigilance 2023

LIFE SCIENCE ACADEMY

# German Pharmacovigilance Day

## Pharmacovigilance: Quo Vadis? Trends and Future Developments

Data
**20 September 2023**

Lingua
**Inglese**

Location
**Frankfurt am Main, Germany**

## INTRODUZIONE

The German Pharmacovigilance Day returns after the pandemic break to catch up on pharmacovigilance topics that evolved in the last 3 years, such as:

- how Artificial Intelligence can help tackle the workload in PV
- new regulations (e.g. EU Clinical Trial Directive) which impact PV activities
- the recent letter from EMA regarding the international transfer of personal (health) data from EudraVigilance
- the implementation of the ISO IDMP Standards
- setting up a global structure of PV System
- how to manage interactions between Headquarter and Affiliates in PV
- the issue of drug shortages

With all these developments, it's important to question "Pharmacovigilance: Quo vadis?" and engage in discussions about future trends and developments in the field.
The German Pharmacovigilance Day provides an opportunity for professionals to come together,

exchange knowledge and experiences, and explore innovative solutions to the challenges faced in pharmacovigilance. By sharing insights and discussing potential solutions, we can collectively advance the field of pharmacovigilance and ensure the safety and well-being of patients.

**Conference language: ENGLISH**

### Scientific Board

- *Marc Zittartz* - Principal Consultant and Managing Director at Insife Germany
- *Carsten Wieser* - Head Global Safety at Dr Falk Pharma

### Who should attend?

The conference program is designed for healthcare professionals or pharmacists working in the pharmacovigilance units in the pharmaceutical industry or regulatory agencies, either as specialists or managers, QPPVs, inspectors and QA personnel including auditors, employees in regulatory affairs units with close relations to pharmacovigilance, vendors and CROs working with patient safety data.

## PROGRAMMA

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| **09:00**<br>**09:30** | **Registration** |
| **09:30**<br>**09:40** | **Welcome by the Scientific Board** |
| **09:40**<br>**10:20** | **Bridging the Two Worlds: Assessing the Impact of the New European Clinical Trial Regulation on Medical Safety and Pharmacovigilance**<br><br>**Zurab Koberidze**<br>Director Pharmacovigilance at FGK Pharmacovigilance GmbH |
| **10:20**<br>**11:00** | **Risk management and effectiveness of RMMs**<br><br>**Dimitris Zampatis**<br>Global Program Safety Lead at Sandoz International GmbH |
| **11:00**<br>**11:30** | **Coffee Break** |
| **11:30**<br>**12:10** | **Challenges of outsourcing local PV activities**<br><br>**Andrea Maulwurf**<br>Head of Corporate Pharmacovigilance Global Leading QPPV at Bencard Allergie GmbH |

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| **12:10**<br>**12:35** | **Managing Interactions between Headquarter and Affiliates in Pharmacovigilance - Focus on Europe**<br><br>**Doris Haarbach**<br>GCSP Region Operation Manager at CSL Behring |
| **12:35**<br>**13:00** | **Hemaya - Pharmacovigilance Awareness Education Program in Middle East & Africa (MEA)**<br><br>**Simone Lorenz-Asmus**<br>Head of PV Regions Europe & Eastern & Central Intercontinental, Middle East Africa at CSL Behring |
| **13:00**<br>**14:00** | **Networking Lunch** |
| **14:00**<br>**14:40** | **A Letter from EMA – International transfer of person (health) data**<br><br>**Marc Zittartz**<br>Principal Consultant and Managing Director, Insife Germany |
| **14:40**<br>**15:20** | **Implementation of the ISO IDMP Standards and its impact on Regulatory and PV departments**<br><br>**Jörg Stüben**<br>Head of Regulatory Information Management and Senior Expert at Boehringer Ingelheim |
| **15:20**<br>**15:50** | **Coffee Break** |
| **15:50**<br>**16:30** | **Drug shortages - a German problem? Background, reasons and solutions**<br><br>**Reinhold J. Schilling**<br>Head of Global Pharmacovigilance, EUQPPV at Wörwag Pharma GmbH |
| **16:30**<br>**17:10** | **ChatGPT as Medical Writer in Pharmacovigilance - Opportunities and Limitations**<br><br>**Heinz Weidenthaler**<br>Global Principal Safety Physician at Bavarian Nordic |
| **17:10**<br>**17:20** | **Conclusions** |

## SPEAKERS

*Scientific Board*
**Marc Zittartz**
Principal Consultant and Managing Director, Insife Germany

*Scientific Board*
**Carsten Wieser**
Head Global Safety at Dr Falk Pharma

*Speaker*
**Zurab Koberidze**
Director Pharmacovigilance at FGK Pharmacovigilance GmbH

*Speaker*
**Doris Haarbach**
GCSP Region Operation Manager at CSL Behring

*Speaker*
**Simone Lorenz-Asmus**
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*Speaker*
**Andrea Maulwurf**
Head of Corporate Pharmacovigilance Global Leading QPPV at Bencard Allergie GmbH

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*Speaker*
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Global Principal Safety Physician at Bavarian Nordic

*Speaker*
**Dimitris Zampatis**
Global Program Safety Lead at Sandoz International GmbH

## QUOTE ISCRIZIONE

**€ 590,00** Early Bird fee until 19 August 2023
**€ 710,00** Ordinary fee
**€ 410,00** Freelance, Academy, Public Administration

**Fee includes:** seat at the conference, .pdf copy of presentations of Speakers who allow the distribution, networking lunch, coffee breaks, organisational office assistance, certificate of attendance.

## DURATA E INFORMAZIONI UTILI

The conference will take place at:

**Hotel nhow Frankfurt**
Brüsseler Str. 1-3, 60327 Frankfurt am Main, Germany

## SEDE DELLA CONFERENZA

**Hotel nhow Frankfurt**
Brüsseler Str. 1-3
60327 Frankfurt am Main, Germany