ONLINE-SEMINAR

FORUM

Pharmacovigilance Signal Management

Detection and evaluation in line with GVP Module IX

Two perspectives, one goal: Practical insights from industry and former regulator

TOPICS

- GVP Module IX inclusive expected updates: content and practical implementation
- Implementing Regulation (EU) 2025/1466
- The signal management workflow based on selected PRAC case examples
- EudraVigilance and EVDAS
- Data analysis with R tidyverse

YOUR SPEAKERS

Larissa Kopp
Self-employed, WHO Consultant

Dr Ulrich Vogel
Boehringer Ingelheim International GmbH

17 - 18 SEPTEMBER 2026 - ONLINE

Aims and objectives

Signal management is a core component of pharmacovigilance and is among the most frequent critical findings during inspections. In this seminar, you will learn how to fulfil regulatory requirements while keeping your processes efficient and lean.

On the first day, the focus is on the regulatory fundamentals and the signal management process. Step by step, the process is worked through and discussed based on practical PRAC examples.

The second day covers advanced topics such as communication with authorities, the use of EudraVigilance, data-driven analyses, digital automation and the role of artificial intelligence in signal management.

A special highlight: Benefit from two complementary viewpoints: The marketing authorisation holder (MAH) perspective from global pharmacovigilance practice and the regulatory perspective from a former assessor.

Who should attend?

This course will be conducted in English.

This online seminar is designed for professionals in pharmaceutical companies who need to understand, implement and apply signal management in pharmacovigilance. The content is suitable both for experienced specialists and for those with initial professional experience.

YOUR SPEAKERS

Larissa Kopp

Self-employed,
WHO Consultant

WHO Consultant in Signal Management and Expert in Pharmacovigilance

With a background in biochemistry and molecular medicine, Larissa Kopp has specialised since 2020 in post-marketing safety assessment of vaccines, monoclonal antibodies and allergen products. Until April 2026, she worked at the Paul-Ehrlich-Institut (PEI), Germany's federal institute for vaccines and biomedicines, where she processed and analysed suspected adverse reaction cases, performed signal management and assessed safety reports. Today she is self-employed and works, among other roles, as a freelance consultant for the World Health Organization (WHO). In addition, she supports the international development and strengthening of pharmacovigilance systems, for example in Lesotho.

Dr Ulrich Vogel

Boehringer Ingelheim International GmbH, Ingelheim

Head Strategic Data Analysis, Global Pharmacovigilance,
Member CIOMS Working Group VIII - Practical Aspects of Signal Detection in Pharmacovigilance

Grounded in his training as a physician, Uli is focusing on transforming pharmacovigilance data into insights for medical risk identification and management. He acts as the global process owner for signal management and Head of the Safety Analytics and Data Science teams in pharmacovigilance. Uli is passionate about (visual) data communication and tailoring access to information in response to stakeholder demands. He is an active coder in R and D3.js and a member of CIOMS Working Group VIII "Practical Aspects of Signal Detection in Pharmacovigilance".

Your programme for both days

09:00-17:00 CE(S)T each day

Introduction to signal management
- Definitions
- GVP Module IX

Workshop: Introduction to selected PRAC case studies

Roles, responsibilities, and process flow - Regulatory and MAH perspective
- Implementing Regulations (EU) 2025/1466 and (EU) 520/2012
- Roles and responsibilities: marketing authorisation holder, national competent authority and EMA
- Decision-making within the EU regulatory network
- PRAC examples (process flow)

Implementing Regulation (EU) 2025/1466 and expected updates to GVP Module IX

Finding, assessing, and presenting signals
- GVP IX Addendum I
- 2x2 contingency table and disproportionality analysis
- Reporting rates and trend analyses
- Quantitative and qualitative methods for medicinal products and vaccines
- PRAC examples (methods)

Decisions and safety actions
- External communication
- PRAC examples (regulatory actions)

Qualitative signal analysis: Causality assessment
- Methods for medicinal products and vaccines
- How quantitative and qualitative signal detection complement each other
- PRAC examples (methods)

EudraVigilance and EVDAS
- Electronic Reaction Monitoring Report
- Regulatory expectations for marketing authorisation holders

Analysing signals efficiently and presenting them clearly
- Regulatory expectations for marketing authorisation holders
- Best practices for signal presentation in regulatory documents
- Common discussion points
- How to avoid follow-up questions

Audits and inspections - Regulatory and MAH perspective

Rule-based automation and artificial intelligence
- Opportunities and limitations
- Current state

Data analysis with R tidyverse
- Analysing eRMRs
- Combining eRMRs with own data
- Calculating reporting rates
- Visualising results
- Or Excel instead? When switching is worth it

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E-mail

Contact person at office

Date, signature

Date
17 - 18 September 2026 - online
09:00-17:00 CE(S)T each day

Fee
€ 2,090.00 (+ German VAT)
The fee includes course material and a participation certificate for download, access to the Learning Space, technical support and a standardised online test including a certificate upon passing.

How our online events work

- Our online events are live and interactive. They can be accessed in the Learning Space, where you will also find the programme, the list of participants and all relevant documents.
- You can access the Learning Space with the same account you use for the customer portal.
- The free pre-meeting helps you resolve any technical issues before the event.
- Continuous support during the online event guarantees that you concentrate entirely on the training.
- We guarantee the highest quality according to ISO 9001 and ISO 21001.

CANCELLATION POLICY

Our general terms and conditions (as of 01 June 2024) apply and are available upon request. We can send them to you at any time. Alternatively, you can access them online at www.forum-institut.com/t&c

YOUR CONTACT

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