1 December 2025
Virtual Training

AKADEMIE HEIDELBERG

Pharmacovigilance Signal Management Fundamentals

Interactive Training

- **Understand key definitions, sources, and the lifecycle of pharmacovigilance signals**
- **Explore detection methods, including statistical and clinical approaches, with real-world examples**
- **Learn how to assess benefit-risk and apply regulatory frameworks from EMA, FDA, and WHO**
- **Gain practical insight into signal tracking tools, documentation, and global reporting timelines**

Practice-based.
Practice-driven.

Speaker

Farima Barmaki Rad
Head of Global Pharmacovigilance and Drug Safety
Freelancer
Basel

Pharmacovigilance Signal Management Fundamentals

Program

Signal Relevant Definitions

- Definitions: Risk, Harm, Signal vs. Risk
- Potential vs. Identified Risks
- Important risks
- Designated Medical Events (DMEs)
- Emerging safety issue
- Hypothesis generation and testing
- Errors in signal assessment

Signal Management Procedures

- Objectives of signal management
- Signal sources (solicited and unsolicited)
- Signal lifecycle: detection to validation to outcome and communications
- Limitations of unsolicited data and points to consider
- Noise effects
- Signals from specific drug utilization (e.g. OTC, Off-Label-Use and medication error)

Signal Detection in Clinical Trials

- Open-label vs masked trials
- Sponsor oversight obligations
- Emerging trends from adaptive trials
- Trial signal workflow example

Signal Detection Methods

- Quantitative and qualitative methods
- Statistical criteria for Signal Detection
- Statistical metrices
- Quantitative Method comparison table

Benefit-Risk Assessment in Signal Context

- Overview of benefit-risk assessment
- Scientific rigor and feasibility
- Key points to consider
- Frameworks and tools
- EMA vs. FDA expectations

Frameworks and Tools in Practice

- Regulator tools, frameworks and company tools
- Signal assessment forms
- Signal tracking systems

Regulatory Requirements, Reporting Signals and Emerging Safety Issues

- Main timelines (EU, US, WHO, etc.)
- Differences in regulatory timelines
- Timeline overview table

Summary, Q&A, Case Wrap-Up

- Q&A, feedback round
- What to remember from each section

Aims and Objectives

This training provides a comprehensive introduction to signal management in pharmacovigilance. Participants will explore the key definitions and regulatory expectations surrounding safety signals, from hypothesis generation to validation, assessment, and communication. The course covers practical aspects of signal detection in both spontaneous and clinical trial data, highlights common pitfalls, and compares qualitative and quantitative detection methods. It introduces core regulatory frameworks and tools used in signal tracking, assessment, and reporting, while emphasizing the importance of scientific rigor in benefit-risk evaluation. Case examples and real-world scenarios will help participants understand how to apply regulatory requirements (EU, FDA, WHO) in day-to-day practice. This seminar is ideal for professionals seeking foundational knowledge in signal management and aims to strengthen their ability to contribute to patient safety in a global regulatory context.

Worth Knowing

Target Audience

This seminar is specifically designed for the following professionals:

- Pharmacovigilance specialists
- Regulatory affairs officers
- Regulatory and legal compliance professionals
- Pharmaceutical industry decision-makers
- External auditors and inspection bodies

Reasons to Join

- You will gain up-to-date know-how on signal management fundamentals specific to pharmacovigilance requirements
- You will receive practical implementation tips for your organization and day-to-day work
- You will clarify individual questions directly with the expert speaker
- You will exchange valuable best practices through with fellow professionals

Our Speaker

Farima Barmaki Rad
Head of Global Pharmacovigilance and Drug Safety
Freelancer, Basel

Physician and global pharmacovigilance expert with over 15 years of leadership experience in clinical practice and the pharmaceutical industry across Europe, the UK, the US, and Asia. Proven expertise in signal management, benefit-risk assessment, and inspection readiness, with a practical focus on developing effective CAPA plans.
Actively involved in research on neurodegenerative diseases and contributions to medical publications. Recognized for applying pharmacovigilance expertise to develop real-world strategies that enhance patient safety and ensure regulatory compliance on a global scale.

Recommended Seminars

Pharmakovigilanz im Produktlebenszyklus
1/2 October 2025, Virtual Training

Budgetkalkulation und Vertragsverhandlungen in klinischen Studien
7 November 2025, Virtual Training

Medizinprodukte-Recht kompakt
10 November 2025, Virtual Training

Good Clinical Practice für AMG-Studien
18 November 2025, Virtual Training

Good Clinical Practice für MPG-Studien
27 November 2025, Virtual Training

MedDRA – Hands-on
24 November 2025, Virtual Training

Good Documentation Practice innerhalb klinischer Studien
3 December 2025, Virtual Training

Programme aus dem EMA-Dschungel mit PV-Relevanz
5 December 2025, Virtual Training

▶ This and other seminar offers can be found online on our website *www.akademie-heidelberg.de/online-seminare*

Further Information

I am happy to answer your questions about this seminar, in-house trainings and our entire program.

Rutkay Azap
Phone 06221/65033-26
r.azap@akademie-heidelberg.de

Registration Form

Pharmacovigilance Signal Management Fundamentals

Surname

First name

Position/Department

Company

Street

Postal code / Town

Phone / Fax

Email

Name of assistant

Date / signature

Please send your registration to: **anmeldung@akademie-heidelberg.de**

Date and Time

Monday, 1 December 2025
9:00 am to 4:30 pm
Online access from 8:45 am

Seminar code: 25 12 PS607 W

Fee

€ 490,– (plus VAT)

The fee includes access to the seminar as well as the presentation as a PDF file.
After the seminar, you will receive a certificate confirming your attendance.

General Terms and Conditions

Our general terms and conditions apply (as of 01.01.2010). If you wish, we can send these to you. An English version is available upon request.
You can also view our general terms and conditions at any time on our website: *www.akademie-heidelberg.de/agb*

Procedure

- One day prior to the seminar you will receive an email with a link giving you direct access to the online seminar.
- In order to participate, you do not need to download and install any program. You can dial in directly via Zoom using your internet browser.
- You can ask questions at any time and discuss them with the speakers and other participants via your microphone and camera. Alternatively, you can use the chat to communicate.

AKADEMIE HEIDELBERG

AH Akademie für Fortbildung Heidelberg GmbH
Maaßstraße 32/1 · 69123 Heidelberg
Telefon 06221/65033-0
info@akademie-heidelberg.de
www.akademie-heidelberg.de

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