2 Decemeber 2025
Virtual Training

AKADEMIE HEIDELBERG

Pharmacovigilance Inspection Readiness and CAPA Fundament

Interactive Training

- **Preparing for national and international PV inspections**
- **Applying regulatory requirements in daily practice**
- **Developing effective CAPAs with strong root cause analysis**
- **Fostering a prevention-oriented quality culture**

Further topics and details inside ▶

Speaker

Farima Barmaki Rad
Head of Global Pharmacovigilance and Drug Safety
Freelancer

Pharmacovigilance Inspection Readiness and CAPA Fundament

Program

Introduction to Inspection Readiness

- Why inspections matter
- Impact of readiness on compliance patient safety

Understanding PV Inspections: Types of Inspections and Regulatory Bodies

- Routine vs. For-Cause vs. Pre-Approval
- FDA, EMA, MHRA, local authorities

Documentation, Systems and Facility Readiness

- Documentation control
- SOPs, TMF and archiving system
- PV Agreements and partner oversight
- Ethics and regulatories compliance
- Signal management system, inspection history and CAPA follow-ups
- Facility walkthrough expectations

Training, Internal Audits and Mock Inspections

- Training Records, CVs, Role Clarity
- Internal Audit Strategy

Preparing the Team and Managing Real-Time Inspections

- Interview Readiness
- Do's and Don'ts during inspection
- Real-time document handling and logistics

Post-Inspection Activities and CAPA-Basics

- Immediate containment
- CAPA framework overview
- Observation – RCA – effectiveness check
- 21 CFR 820.100, ISO 13485, ICH Q10

CAPA Deep Dive – Lifecycle and Process Flow

- Problem identification
- Root cause analysis methods (5 Whys, Fishbone, FMEA)
- Corrective vs. preventive actions
- RCA templates
- CAPA form layout

Writing Good CAPAs and Regulatory Expectations

- SMART CAPAs
- Common pitfalls: Vague actions, no ownership
- Auditor/Inspector expectations
- SMART action examples
- Audit Q&A checklist
- ISO, FDA warning letter extracts

Writing Good CAPAs and Regulatory Expectations

- CAPA tracking and change control
- Leveraging near misses and learning opportunities
- Embedding a prevention-oriented mindset
- Ensuring change control support sustainable CAPA implementation
- Quality metrics dashboard example

Wrap-Up and Summary

Aims and Objectives

This seminar provides a practical foundation for achieving inspection readiness in pharmacovigilance (PV) and implementing effective Corrective and Preventive Actions (CAPA). Participants will gain a comprehensive understanding of inspection types, key regulatory expectations, and how to prepare documentation, systems, and teams.

Core elements include handling real-time inspections, audit strategies, and aligning CAPA processes with international standards such as FDA 21 CFR 820.100, ISO 13485, and ICH Q10.

Through real-world examples and actionable tools, attendees will learn how to identify root causes, avoid common CAPA pitfalls, and drive sustainable quality improvements. The seminar empowers PV professionals to enhance compliance, ensure patient safety, and foster a preventive, inspection-ready culture within their organizations.

Worth Knowing

Target Audience

This seminar is specifically designed for professionals working:

- 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 pharmacovigilance requirements specific to Inspection Readiness and CAPA Fundamentals
- 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 benefit from valuable best practices through exchange 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.

Budgetkalkulation & 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.

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m.mueller@akademie-heidelberg.de

Registration form

Pharmacovigilance Inspection Readiness and CAPA Fundamentals

First name

Name

Position / Department

Company

Adress

Postal Code / City

Telefone

E-Mail

Assistant's name

Date / Signature

Kindly send your regsitration to: **anmeldung@akademie-heidelberg.de**

Date and Time

Tuesday, 02 December 2025
9:00 am to 4:30 pm
Online access from 8:45 am
Seminar code: 2512PS606W

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.

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