30th November 2026 · 9:00 a.m.–3:00 p.m.
Virtual Training

AKADEMIE HEIDELBERG

Inspection Preparedness and CAPA Planning Across Global Regulatory Environments

Regulatory and Industry Best Practices

- Practical Approaches to PV Inspections, Findings, and CAPA
- Overview and Oversight of PV Inspections
- Case Management, Signal Management and Aggregate Reports
- Dos and Don'ts
- Corrective and Preventive Actions (CAPA)

Speaker

Philipp Ansorge
Head Pharmacovigilance
Market Access Lead, Luminance Health
Basel, Switzerland

Joanna Hanley
Head Quality Assurance
Luminance Health
Basel, Switzerland

Inspection Preparedness and CAPA Planning Across Global Regulatory Environments

Program

- Governance and Oversight
  - QPPV roles and responsibilities, PSMF maintenance, and global PV oversight
  - QMS requirements and best practices
  - Inspection readiness strategies and governance frameworks
- Case Management and Safety Database
  - End-to-end ICSR management, including intake, processing, medical review, coding, and QC
  - Expedited reporting requirements, timelines, and compliance monitoring
  - Safety database governance and literature surveillance
- Contractual Agreements/PV Agreements and Complianc
  - PVAs and SDEAs, including safety data exchange requirements
  - Roles, responsibilities, and vendor/partner due diligence
  - Compliance monitoring and oversight of outsourced activities
- Signal Management
  - Signal detection, validation, prioritization, and assessment
  - Signal management governance and decision-making processes
  - Signal trackers, documentation, and reporting requirements
  - Signal communication and escalation pathways
- Aggregate Reports and Risk Management
  - Preparation and quality oversight of PSUR/PBRER and DSUR
  - RMP development and maintenance
  - Consistency of safety data across submissions
- Labelling and Reference Safety Information
  - Safety-driven labeling updates and change management
  - CCDS governance and consistency with other RSI
  - Implementation and maintenance of RSI
- Clinical Trial Safety
  - Sponsor responsibilities and clinical safety database oversight
  - Safety considerations for informed consent and reporting compliance
  - Governance of clinical trial safety activities
- Cross-Functional Collaboration
  - Collaboration with Cross-functional teams
  - Alignment with Regulatory Affairs
  - Safety issue escalation and communication pathways
- Local Affiliate Readiness
  - Affiliate pharmacovigilance inspection readiness
  - Implementation of RSI and RMP requirements
  - Headquarters governance
- Regulatory Expectations and Dos and Don'ts
  - Inspection logistics, personnel training, and process oversight
  - Appropriate behavior during inspections and key expectations
  - Common findings and regulatory categorization of inspection outcomes
- Corrective and Preventive Actions (CAPA)
  - CAPA components, root cause analysis, and risk-based implementation
  - Regional and regulatory considerations for PV compliance
  - CAPA tracking, effectiveness checks, and continuous improvement

Aims and Objectives

This webinar provides a comprehensive overview of pharmacovigilance (PV) inspection preparedness and readiness across major global regulatory jurisdictions. Participants will gain practical insights into regulatory expectations, governance frameworks, quality systems, and operational processes that support a compliant and inspection-ready PV system.
The session will examine critical pharmacovigilance activities, including QPPV oversight, Pharmacovigilance System Master File (PSMF) management, Quality Management System (QMS) requirements, case processing and reporting compliance, safety database oversight, signal management, aggregate reporting, risk management planning, labeling governance, and clinical trial safety obligations. It will also address the management of pharmacovigilance agreements, vendor and affiliate oversight, and effective cross-functional collaboration with Regulatory Affairs.
In addition, participants will review common inspection findings, compare regulatory approaches across regions, and explore best practices for developing, implementing, and monitoring effective Corrective and Preventive Actions (CAPAs). The webinar is designed to help organizations strengthen compliance, mitigate inspection risks, and maintain sustainable pharmacovigilance inspection readiness throughout the product lifecycle.

Worth knowing

Target audience

- PV/Drug Safety, QA/QM, GxP Auditing, Regulatory and Medical Affairs
- Clinical Safety/Operations and Development, Signal and Risk Mgmt, Case Processing, CROs/PV Service Providers
- QPPV Offices, Local Safety Officers, Vendor and Alliance Mgmt
- Pharma, Akademia, Biotech and Medical Device Companies

Good reasons to attend

- Gain up-to-date knowledge on PV inspections and CAPAs, with practical implementation tips and the opportunity to clarify open questions with the speaker
- Benefit from valuable best practices and exchange with other professionals to support your department or organization

Our Speaker

Philipp Ansorge
Head Pharmacovigilance, Market Access Lead
Luminance Health, Basel, Switzerland

Philipp Ansorge is Head of Pharmacovigilance and Pharmacovigilance Responsible Person at Luminance Health, providing strategic support across Quality Assurance and Pharmacovigilance. He develops and implements compliant PV systems and advises clients on regulatory requirements and safety risk management.
Throughout his career, Philipp has held numerous mandates, including Swiss Responsible Person (Medicinal Products and ATMPs), Pharmacovigilance Responsible Person, EudraVigilance Responsible Person, and EU-QPPV. He is also an experienced auditor and has successfully hosted several health authority inspections.

Joanna Hanley
Head Quality Assurance, Luminance Health, Basel, Switzerland

Joanna Hanley is Head of Quality Assurance and Responsible Person at Luminance Health. She develops and implements pharmaceutical Quality Management Systems compliant with global regulations and GxP standards, providing tailored solutions for organizations across all stages of the product lifecycle.
Joanna has served as Responsible Person on various Swiss establishment licenses, including for small molecules, blood products, biologics, and ATMPs, ensuring compliant global supply chains. She has successfully supported the acquisition of manufacturing and distribution licenses across the EU, UK, and Switzerland and advises organizations on quality compliance and continuous improvement through tailored training and audit services.

MedDRA – Hands-on
22. September 2026, Online-Veranstaltung

Women in Research – Empowerment, Visibility and Mental Strength
6. Oktober 2026, Online-Veranstaltung

Programme aus dem EMA-Dschungel mit PV-Relevanz
27. Oktober 2026, Online-Veranstaltung

Was nicht im Risk Management Plan steht
10. November 2026, Online-Veranstaltung

Beton meets BtM: Pharmabauprojekte
1. Dezember 2026, Online-Veranstaltung

DSUR and PSUR/PBRER
4. Dezember 2026, Online-Veranstaltung

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

Further Information

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

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Registration Form

Inspection Preparedness and CAPA Planning Across Global Regulatory Environments

Last Name

First Name

Job Title

Company / Orgnaization

Street Address / No.

Postal Code / City

Phone Number

Email Address

Assistant's Name

Date / Signature

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

Date and Time

30th November 2026
9:00 a.m. to 3:00 p.m.
Online access from 8:45 a.m.
Seminar code: 26 11 PS714 W

Fee

€ 990,– (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.

Special fee: € 890 ,– (plus applicable VAT) for registrations received by August 31, 2026.

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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