1st March 2027 · 9:00 a.m. – 3:00 p.m.
Virtual Training

AKADEMIE HEIDELBERG

Pharmacovigilance Audits

Ensuring PV Compliance Through Effective Audit Strategies

Regulatory Expectations and Industry Best

- **Overview and Conduct of PV Audits: Purpose, scope, preparation, execution, reporting, and follow-up**
- **Legal Framework: Key PV regulatory requirements and GVP expectations**
- **Audit Strategy and Risk-Based Planning: Risk assessments and prioritization of PV activities, systems, and vendors**
- **Common Deficiencies and Case Studies: Typical inspection findings and practical examples**

Speaker

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

Anastasia Agapouda, PhD
Senior Manager Quality Assurance & Pharmacovigilance
Luminance Health, Basel, Switzerland

Pharmacovigilance Audits

Program

Overview of PV Audits

- Role of PV audits in ensuring GVP compliance, inspection readiness, and continuous quality improvement
- Purpose, strategic value, scope, and lifecycle phases of pharmacovigilance audits across PV systems and processes

Legal Framework

- Overview of the regulatory framework hierarchy and key pharmacovigilance requirements in the EU and international markets
- Important regulations, regulatory expectations, and practical implementation within daily PV operations and oversight activities

Governance of Pharmacovigilance Audits

- Contractual audit clauses, responsibilities, and oversight of third parties, vendors, and service providers
- Mandatory PV roles, governance structures, escalation pathways, and governance best practices supporting compliance

Aspects of the Quality Management System (QMS)

- Core QMS documents, SOP requirements, and documentation standards relevant to pharmacovigilance audits
- Audit documentation, audit report structures, and considerations for external and internal PV audits

Audit Strategy and Risk-Based Audit Planning

- Development of risk-based audit approaches aligned with GVP expectations and regulatory requirements
- Audit planning methodologies based on vendor criticality, compliance risks, process complexity, and previous findings

Conducting Pharmacovigilance Audits

- Types of PV audits, including internal, external, system, process, and vendor audits
- Practical approaches to audit preparation, execution, interviewing techniques, reporting, and communication of findings

Findings, CAPAs and Follow-up

- Classification and management of audit findings and development of effective CAPA plans
- Follow-up activities, root cause considerations, effectiveness checks, and monitoring of CAPA implementation

Common Findings in Regulatory Inspections

- Current trends, recurring deficiencies, and inspection observations identified by EMA and MHRA inspectors
- Practical lessons learned and measures to strengthen inspection readiness and sustainable compliance

Audits, Inspections and the PSMF

- PSMF requirements, regulatory expectations, and practical implementation considerations within PV systems
- Regulatory consequences, inspection impact, and compliance risks associated with audit findings and inadequate oversight

Aims and Objectives

This webinar provides a practical and comprehensive overview of pharmacovigilance audits within the EU regulatory framework and current GVP expectations. Participants will gain insight into the purpose, governance, and strategic value of PV audits, including their role in ensuring compliance, inspection readiness, and continuous quality improvement. The programme covers risk-based audit planning, audit preparation and conduct, reporting, and the management of findings and CAPAs. In addition, participants will explore the integration of audits into the Pharmacovigilance System Master File (PSMF) and the Quality Management System (QMS), including the oversight of vendors and third parties. Practical examples, real-world case studies, and common regulatory inspection findings will help participants translate regulatory expectations into effective audit practices.

Key benefits:

- Gain up-to-date knowledge on PV audit requirements, risk-based planning, CAPA management, and audit integration into the PSMF and QMS.
- Receive practical implementation tips that can be applied directly in your organisation.
- Discuss your own questions with the expert and exchange experiences with fellow professionals.

Reasons to Join

Target audience

- Pharmacovigilance and Drug Safety personnel
- Quality Assurance and Quality Management personnel
- Regulatory Affairs personnel
- Clinical Safety and Clinical Operations
- Auditing and GxP Quality Functions
- Medical Affairs personnel
- Pharmacovigilance Service Providers
- Pharmaceutical, Biotechnology, and Medical Device Companies as well as other interested departments or key areas, executives/board members and external auditors

Our Speaker

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

Philipp Ansorge is the Head Pharmacovigilance and Pharmacovigilance Responsible Person at Luminance Health and provides cross-functional strategic advice across Quality Assurance and Pharmacovigilance. He leads the development and implementation of robust pharmacovigilance systems that ensure the safety and compliance of pharmaceutical products throughout their lifecycle. With his broad knowledge of the regulatory requirements for drug safety in various jurisdictions, he provides guidance to clients, ensuring timely identification, evaluation, and mitigation of safety risks.
Philipp has successfully taken on numerous mandates throughout his career. These include roles such as Swiss Responsible Person (for Medicinal Products and ATMPs), Pharmacovigilance Responsible Person, EudraVigilance Responsible Person, and EU-QPPV. Philipp is an experienced auditor and has successfully hosted several inspections by health authorities.

Anastasia Agapouda, PhD
Senior Manager Quality Assurance & Pharmacovigilance
Luminance Health, Basel, Switzerland

Anastasia Agapouda, PhD, is Senior Manager Quality Assurance and Pharmacovigilance and Deputy Responsible Person for Pharmacovigilance at Luminance Health. She specialises in implementing and maintaining Pharmacovigilance and Quality Management Systems in line with global regulatory requirements. With extensive experience in PV system set-up, gap analyses and inspections, she has also served as Deputy Responsible Person for various clients and supported successful Swiss health authority inspections.

MedDRA – Hands-on
September 22, 2026, Online Event

Women in Research – Empowerment, Visibility and Mental Strength
October 6, 2026, Online Event

Programme aus dem EMA-Dschungel mit PV-Relevanz
October 27, 2026, Online Event

Was nicht im Risk Management Plan steht
November 10, 2026, Online Event

Beton meets BtM: Pharmabauprojekte
December 1, 2026, Online Event

DSUR and PSUR/PBRER
December 4, 2026, Online Event

▶ 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

Pharmacovigilance Audits

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

1st March 2027
9:00 a.m. to 3:00 p.m.
Online access from 8:45 a.m.
Seminar code: 27 03 PS7162 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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