25th GLOBAL MEETING

San José, Costa Rica 2026

Ecosystems of trust: Pharmacovigilance for a healthier world

AGENDA

Pre-Conference Training Courses

Registration fees:

Full-day courses

$150.00 USD

Lunch included

Half-day course

$80.00 USD

Coffee included

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Pre-conference training course 1: Leading with Confidence: Essential Leadership Skills for Pharmacovigilance

Learn about fundamental leaderships skills, how these can be applied in a PV context, pathways to leadership in PV, how to lead effectively during challenging situations, and strategies to support your personal leadership development. By the end of the course, you will also be equipped with tools and strategies that you can use to continually hone your approach to leadership.

Target audience: The course is relevant to anyone looking to strengthen their leadership abilities, from students and early career professionals, through to experienced PV specialists.

Objetives: To equip participants with the fundamental skills to succeed in leadership roles in PV and to agree a shared definition of good leadership in PV.

8:30	**Registration**
9:00	**Welcome and framing of the day**
9:30	**Why does leadership matter in PV?**
10:45	**Coffee Break**
11:15	**Pathways to leadership**
12:15	**Lunch Break**
13:15	**Leadership under pressure: responding to challenges**
15:15	**Coffee Break**
15:45	**Personal leadership development**
16:45	**Course close**

Pre-conference training course 2
Signal Management in Practice: From Detection to Decision-Making

The course will enable participants to detect and assess signals effectively and to apply signal assessment approaches to support transparent and robust regulatory decision-making that prioritises patient safety.

Participants may choose to attend part 1 only, or the full-day programme, depending on their learning needs and level of experience. Participants who complete the full-day course and meet the requirements outlined in the end-of-day assessment will receive an official certificate of completion issued by Uppsala Monitoring Centre and ISoP, recognising advanced training in pharmacovigilance signal management.

Target audience: Industry and regulatory pharmacovigilance professionals; Qualified Persons Responsible for Pharmacovigilance (QVs), safety scientists and medical reviewers; researchers and academics working with real-world data and drug safety.

Objective: To equip participants with practical skills in pharmacovigilance signal management, enabling them to detect and assess signals effectively and to support transparent and robust regulatory decision-making that prioritises patient safety.

Prerequisites: Before attending the course, participants are expected to complete five online introductory courses that establish the essential concepts and terminology required for effective engagement in the in-person training sessions. Further details on the specific courses will be shared with participants after registration.

8:00	**Registration**
8:30	**Opening & Course objectives**
8:40	**Overview of Signal Management Process**
9:40	**Signal Detection (incl. case example and group exercise)**
10:30	**Coffee Break**
11:00	**Signal validation and prioritisation (incl. case example and group exercise)**
12:00	**Lunch Break**
13:00	**Signal assessment** **a. Individual case assessment (incl. Hands-on exercise)**
13:40	**Signal assessment** **b.Case series assessment (incl. Hands-on exercise)**

Pre-conference training course 2
Signal Management in Practice: From Detection to Decision-Making

14:20	**Coffee Break**
14:35	**Signal assessment** **b. Case series assessment – continuation - Hands-on exercise**
15:30	**Signal Assessment Conclusion,** **Regulatory Actions and Next Steps**
16:30	**Closing Panel and Feeback**

Pre-conference training course 3
FDA's AEMS and UMC's VigiBase: Foundational and Practical Approaches to Global Safety Surveillance

Coordinated by experts from the United States Food and Drug Administration (FDA) and Uppsala Monitoring Centre (UMC), this half-day course will address foundational and practical approaches to global safety surveillance using FDA's Adverse Event Monitoring System (AEMS) and the UMC's VigiBase. AEMS and VigiBase are critical resources for postmarket drug safety surveillance. They are large-scale platforms that aggregate adverse event data from diverse sources to support ongoing safety assessment across regulatory and global contexts. This course provides a comprehensive overview of both systems, from data collection to practical data analysis.

Target audience: This course is designed for pharmacovigilance experts across regions, industry professionals, academic researchers, and regulators who work with or have an interest in global adverse event surveillance systems and postmarket drug safety monitoring.

Objectives:
- Describe the frameworks and recent updates governing adverse event reporting to AEMS and VigiBase
- Explain database characteristics, strengths, limitations, and appropriate applications for both systems
- Identify factors affecting reporting patterns over time and their impact on signal interpretation
- Navigate the AEMS public dashboard and apply best practices for data analysis
- Apply innovative analytical approaches, including methods for identifying special populations in adverse event data
- Analyze case examples demonstrating practical applications in global pharmacovigilance.

8:00	**Registration**
8:30	**ICSR Foundations: Regulatory Frameworks and Database Fundamentals**
9:15	**Beyond the Numbers: Interpreting Reporting Patterns and Emerging Methods**
10:00	**Coffee Break**
10:30	**Hands-on Dashboard Navigation and Data Analysis Best Practices**
11:15	**Real-World Case Studies and Interactive Discussion**

Pre-Conference Training Course 4
Winning strategies for PV Audits: Compliance, Inspection Readiness and Risk Management.

In today's evolving regulatory environment, Pharmacovigilance (PV) audits and inspections have become increasingly complex, risk-driven, and globally interconnected. Organizations must move beyond reactive compliance and adopt proactive strategies that ensure continuous inspection readiness, effective risk management, and operational excellence.

Learn about audit planning and scope definition, PV system inspections, GVP Module IX compliance, deviation management, CAPA development, regulatory inspection conduct, and audit trail documentation through practical exercises and case studies.

Target audience: This course is aimed at professionals with expertise in Pharmacovigilance Professionals, PV Quality Assurance Teams, QPPVs and Local Safety Officers, Regulatory Affairs Professionals, Compliance Managers, Clinical Safety & Risk Management Teams, CRO and MAH Representatives and Auditors and Inspection Readiness Leads.

Objective: His half-day course will address the planning, conduct, and management of audits and inspections of pharmacovigilance systems, with a focus on ensuring compliance with Good Pharmacovigilance Practices (GVP), global regulatory requirements, and continuous quality improvement.

7:30 **Registration**

8:00 **The New Era of PV Audits & Inspections**

Theory Session
- Global inspection trends and regulatory expectations
- GVP Module IX overview
- Common findings from health authorities
- Critical inspection risk areas
- Inspection culture vs compliance culture

Interactive Activity
- "Are You Inspection Ready?" self-assessment exercise

10:00 **Risk-Based PV Auditing Strategies**

Theory Session
- Risk-based audit methodologies
- Vendor and affiliate oversight
- Audit scope definition
- Data integrity and signal management risks
- KPIs and compliance metrics

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10:00 **Practical Workshop**
- Group exercise: Building a risk-based audit plan
- Case study analysis of a failed inspection

12:00 **Lunch**

13:00 **Inspection Readiness Excellence**

Theory Session
- Building sustainable inspection readiness programs
- Documentation and evidence management
- Preparing SMEs and interview techniques
- Health authority expectations during inspections
- Remote and hybrid inspections.
- AI to identify high risk PV processes.

Practical Simulation
- Mock inspector interview exercise
- Inspection response role play

14:30 **Managing Critical Findings & CAPAs**

Theory Session
- Root cause analysis methodologies
- Writing effective CAPAs
- Escalation and governance models
- Preventing repeat findings
- Communication with regulators

Hands-On Exercise
- CAPA drafting workshop using real inspection scenarios

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16:00 **Advanced Workshop: Inspection crisis simulation.**

Integrative Group exercise

Simulation:

Major compliance findings
Escalation management
Health authority questions
Vendor oversight gaps
Data integrity concerns
Executive communication challenges