300€
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Pharmacovigilance Without Borders

Global Safety Oversight, Governance, and Compliance Across European and Arab Markets

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Key Topics

- Regulatory Frameworks
- PV Best Practices
- Partnerships and Contracts
- Preparing an Inspection
- Documentation Requirements

Course Facilitators

- Dr Bianca Scholz, ScholzPharma GmbH, Germany
- Susan Timeus, Tillotts Pharma AG, Switzerland
- Prof Saleh Bawazir, Bawazir Pharma Consult Center, Saudi-Arabia

April 13 - 14, 2026

Webinar

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Agenda

Day 1: 9.00 a.m. – 5.00 p.m.

Day 2: 9.00 a.m. – 5.00 p.m.

All times according to CET (Central European Time).

Breaks will be arranged flexibly.

Content of the Course

Pharmacovigilance is increasingly shaped by international collaborations. This course focuses primarily on two regions, each complex in its own right and encompassing numerous countries and thus legal systems: Europe and the GCC (Gulf Cooperation Council). The course addresses the regulatory frameworks as foundations. Furthermore, it focuses on operational challenges. It takes into account that companies — i.e. the MAHs —must leverage regional synergies while simultaneously encountering country-specific details. Our seminar leaders, drawing on their diverse regional projects and extensive experience, will explore how structures can be developed and compliance ensured in these contexts.

The Regulatory Landscape: an Overview

- EU/UK/CH PV obligations for global safety oversight
- Overview of regional PV requirements:
  - GCC (Gulf Cooperation Council) : UAE, Saudi Arabia, Qatar, Kuwait, Oman, Bahrain
  - Levant: Jordan, Lebanon, and others
- Local QPPV/LSO (Local Safety Officer) requirements in Arab countries
- Requirements for reporting: domestic vs foreign cases

Roles and Responsibilities Across the PV Network

- Global MAH responsibilities
  - EU
  - United Kingdom
  - Switzerland
- Local MAH responsibilities: where are they applicable?
- Distributor responsibilities in Non-MAH markets
- Safety data flow: timelines, the format, and minimum data elements
- Escalation pathways for serious and critical events

PV Agreements and Contract Governance

- Required components of PVA
  - Safety data exchange
  - Timelines for key elements (ICSRs, complaints, recalls, signals)
  - Local regulatory reporting obligations
  - Inspections and audits
  - Training requirements
- Managing multiple distributors in different Arab jurisdictions
- Change control and version management
- Oversight by the global MAH

Safety Data Collection and Global Database Management

- What is expected from distributors?
  - AE/SAE collection processes
  - Documentation standards
  - Handling of literature cases
- Transfer of data to the global safety database
- Duplicate detection and case reconciliation
- Data privacy considerations
  - The EU's GDPR
  - Relevant local laws and legal frameworks

Local Reporting Requirements in Arab Countries

- Case reporting
  - Serious or non-serious
  - Local vs foreign reporting
- Device vigilance (if applicable)
- Periodic reporting (PSUR, PBRER, RMP updates)
- Product quality complaints and defect reporting
- Variability across agencies (SFDA, MOHAP, DHA, DoH, JFDA, etc.)

Local Aspects in Saudi-Arabia: PV Compliance and Inspection Readiness

- PV: local requirements
- Relevant authorities in Saudi-Arabia
- Inspection readiness and preparation
- Experiences so far

Prof Saleh Bawazir, Professor of Clinical Pharmacy, CEO, Bawazir Pharma Consult Center, Consultant GCC Regulatory Affairs, Saudi-Arabia

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Inspection and Audit Readiness

- Common inspection triggers
  - EU/UK/Swiss
  - Arab countries: the US FDA
- Distributor expectations during inspections
- MAH oversight responsibilities
- Document management: SOPs, training, logs, case files
- Mock inspection preparation
- Inspection communication strategies

Signal Management and Risk Minimization

- Distributor responsibilities in signal detection support
- Local intelligence and pharmacovigilance insights
- Implementation of local risk minimization measures
- Communication to HCPs: safety alerts, DHPCs, recalls

Product Complaints, Recalls and Quality Defect Handling

- PV–Quality–Regulatory interface
- Complaint intake and triage
- Linking complaints to safety cases
- Local recall procedures (UAE, Saudi Arabia, Egypt, etc.)
- Joint responsibilities for FSCA/product withdrawal

Training and Competency Requirements

- Mandatory annual PV training for distributors: what is required?
- Documentation of competencies
- Training materials provided by MAH vs locally prepared and specific requirements

Governance Model and Performance Monitoring

- KPIs and metrics for distributors' PV performance
- Case reporting timeliness
- Compliance tracking
- Periodic performance review

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Your Course Facilitators

Dr Bianca Scholz, Managing Director, ScholzPharma GmbH, Germany
Bianca is Managing Director of Scholzpharma GmbH since 2008 and advises clients in the areas of GVP, GCP, GLP, GDP and GMP as well as ISO with a focus on quality management, audit and inspection worldwide. Prior to founding her own company she worked for Baxter Healthcare (2002-2008) as Quality Manager/Auditor in the Team of Corporate Compliance Services. She was Lead Auditor for Pharmacovigilance audits (GVP) and audits of clinical trials (GCP) and supported the Team as Subject Matter Expert in other GxP fields (GMP, GLP, GDP).
Bianca is DGQ/EQO certified auditor, specialised pharmacist for drug information and carries out numerous audits in the field of GxP/ISO (including inspection preparations/"inspection readiness"). Bianca prepared, supported and attended as a consultant several inspections by Competent Authorities worldwide covering the Asian, European and US market.

Susan Timeus, Head of Drug Safety, Tillotts Pharma AG, Switzerland

Susan is the team lead of Tillotts Pharma AG in Switzerland. She has been working in the area of Drug Safety since more than 20 years. She leads a team responsible for implementing and maintaining a GVP compliant system for products marketed in the Switzerland, EU, UK and worldwide via partners. She manages all operational functions within the Pharmacovigilance department including preparing and maintaining Standard Operating Procedures (SOPs), risk-based Audit Strategies, ICSRs reporting including compliance monitoring, aggregate reporting, signal detection processes, literature searches and monitoring, Pharmacovigilance Agreements, Risk Management Plans and Pharmacovigilance System Master File (PSMF). She provides expertise on how companies can implement and maintain a robust PV system.

Prof Saleh Abdullah Bawazir, Bawazir Pharma Consult Center, Saudi-Arabia

For more than 12 years Prof Bawazir worked as an advisor to the Executive Office for the Health Ministers of the Arabian Countries on the Gulf.
During his work he chaired the committee that revised and updated the pharmacy law and updated drug registration procedures. He also represented the Ministry of Health in the national committee that negotiated Saudi Arabia's accession to the World Trade Organization (WTO) and the committee that established the Saudi Food and Drug Authority (SFDA). Prof Bawazir is considered an authority in pharmaceutical regulations in Saudi Arabia and the GCC. Prof Bawazir has more than 200 publications and presentations in scientific meetings and journals and three books.

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Venue

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Pharmacovigilance – Arab, EU, US

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