400€
Early bird discount until
September 5, 2025

Pharmacovigilance Quality Management Training

Arab - EU - US

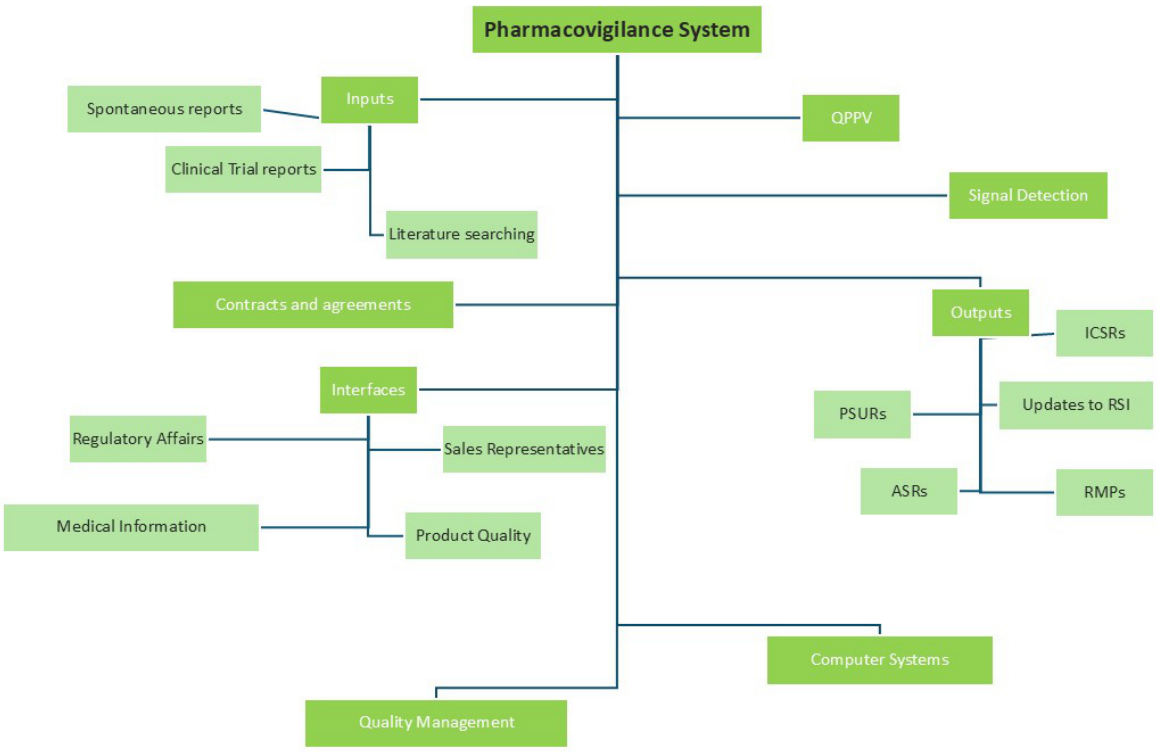
www.chem-academy.com

Key Topics

- Regulatory Frameworks: MENA, EU, US
- 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



November 3 - 5, 2025

Dubai, UAE

an event of the Chem Academy

www.chem-academy.com/pva

Agenda

Day 1: 9.00 a.m. – 5.00 p.m.

Day 2: 9.00 a.m. – 5.00 p.m.

Day 3: 9.00 a.m. – 4.30 p.m.

Breaks will be arranged flexibly.

Content of the Course

Day 1 - Monday, November 3

This course enables participants to understand, implement, and improve the PV system in a highly demanding environment. Its facilitators share their experiences from decades in PV functions, reflecting both lessons learnt and ongoing changes within the regulatory frameworks.
PV systems in place, e.g. in the EU and the US, have grown over long periods, coined by Best Practices and established standards. This is a challenge of its own and requires constant work on the concept as well as on the toolbox at disposal. However, an additional key factor is the management of partners (internal and external) and authorities.
The course provides an overview of the numerous tasks PV has to cope with. It helps to understand what needs to be done and why; and it helps to maintain compliance, including in depth experiences with inspections by contract partners and Competent Authorities.
The course facilitators have specialised in these areas and share their knowledge in 3 intense days, including a complex documentation.

1. Introduction to Pharmacovigilance: Regulatory Requirements and where they come from

- Basics and general expectations in Good Vigilance Practice
- Pharmacovigilance (PV): Who is in charge of what?
  - Organisational schemes
  - Local PV contact persons
  - Qualification and training measures
  - 24/7 availability
- What do NCAs (National Competent Authorities) expect?
  - Experiences with Arab, other domestic and international authorities so far
- Examples for Dos and Don'ts as a local PV contact

2. PV Requirements in MENA (Middle East and North Africa)

- Country specific requirements
- The registration process and legal requirements
- Contract specific requirements
- Typical contract templates
- Contract management: key elements and potential stumbling blocks

3. Partnerships with MAHs Located in the EU

- What do EU based partners (MAHs, Marketing authorisation holders) expect from PV partners?
- Obligations: EU and Arab countries – commonalities and differences
- Local specific regulations in the regulatory context of the EU market
- The role of the EU QPPV (Qualified Person for Pharmacovigilance)
- Compliance challenges
  - Key performance indicators
  - Typical contracts
  - Challenges with international partnerships

Following the official part of the conference, Chem-Academy invites you to a social evening reception. Benefit from the informal surrounding to intensify business contacts and extend your network.

Day 2 - Tuesday, November 4

4. Partnerships with MAHs Located in the US

- What do US based MAHs expect from PV partners?
- The US FDA (Food and Drug Administration): obligations
- Local specific regulations in the regulatory context of the US market
- Compliance challenges
  - Key performance indicators
  - Typical contracts
  - Challenges with international partnerships

5. Monitoring of Medicine in the Market

- Monitoring in the target market
- Indicators for the maturity of a regulated healthcare market
- How to identify customer's needs, and how to assess complaints
- How to trend customer satisfaction (ISO 9001)
- Typical adverse events (AEs) and experience in assessment of these
- How to serve PV expectations in the daily business
- Assessing patient's feedback: behavior, typical complaints, and actual safety issues
- Processing PV relevant information
- PV's role in case of a product recall

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6. Safety Database

- Relevant applications
  - EudraVigilance: the EMA's (European Medical Agency) system for information on suspected adverse reactions
- Validation of digital systems
- The interface from principal to partner
- Reconciliation process

Day 3 - Wednesday, November 5

7. Processes and the Toolbox for PV

- Defining processes for PV compliance
- Case intake and case report management
  - What is the role of the QPPV?
  - Follow-up
- Signal Management
- Literature searches
- Periodic Safety Update Report (PSUR)
- Risk Management Plans (RMPs)
- Business Continuity Plan in Pharmacovigilance
- Deviation Management
- Pharmacovigilance System Master File (PSMF)

8. Pharmacovigilance Documentation

- Good Documentation Practice
- Implementing a Quality Management System
  - Key elements of ISO 9001
- Electronic and paper-based documentation
- Data Management
  - Data Protection Requirements
  - European data requirements and expectations by partners and NCAs
  - Retention of Safety relevant data
  - Traceability and retrievability
  - Source Data Verification
  - How to exchange data with partners from different regulatory frameworks

9. PV Inspections

- What does "inspection readiness" mean?
- Preparing for inspections
- Typical questions during inspections
  - Lessons learned from inspections by the US FDA and European authorities
- Dos and Don'ts before, during and after inspections
- Proper CAPA management (Corrective and Preventive Action)

Your Course Facilitators

Dr Bianca Scholz, Managing Director, ScholzPharma GmbH

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

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.

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Post	Chem-Academy
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	Bahnhofsplatz 2, D-16321 Bernau bei Berlin

Venue

Le Meridien Dubai Hotel & Konferenzzentrum
Airport Road
PO Box 10001 Dubai
United Arab Emirates
Website: https://www.marriott.com/en-us/hotels/dxbmd-le-meridien-dubai-hotel

Terms and Conditions

1. Registration
Registration is confirmed in writing by the organisers. The registration fee covers attendance at the lectures for the number of days selected, full documentation, entrance to the exhibition area, lunch and refreshments. VAT has to be added. Important note in terms of late payment: As mentioned in the registration form all payments must be received within the due date given in the invoice. If you assume that your company is not able to manage payment in-time by bank transfer, please provide your credit card details in order to guarantee your booking. This helps to avoid any inconvenience upon your arrival at the event. At that time the full amount of the payment must be received in our accounts at latest. Thank you very much for your co-operation.

2. Cancellations
Cancellations of a registration by a delegate has to be received in writing at least 30 days prior to the event and will be subject to a service charge of 200 Euro. Substitutions are acceptable at any time. Where cancellations are received later, the registration fee remains payable in its entirety. In case the event has to be cancelled by the organiser payments already received will be credited for the following year's event.

3. Copyright
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4. Liability
It may be necessary for reasons beyond the control of the organiser to alter the content or the timing of the programme or to cancel the event. The organiser of the event is not liable to pay any compensation or damages resulting from alteration, cancellation or postponement of the event. The organiser will do the upmost to inform the delegates of such modifications as early as possible, but is especially not liable if higher force or unforeseen incidences are affecting the meaningful implementation of the event. Force majeure includes: armed conflicts, civil strife, terrorist threats, natural disasters, political constraints, significant influence of transport, etc.

5. Data Protection
The organiser gathers and processes data in accordance with data protection laws. Your data is stored electronically for the purpose of future updates of our services. If you wish your data to be amended, removed or not passed to an external organisation, please write to info@chem-academy.com.

6. Final Clauses
The contract is subject to the German law. Area of jurisdiction is Bernau bei Berlin, Germany.

Pharmacovigilance – Arab, EU, US

Yes, I hereby register bindingly for:

	Early Bird	Regular price
☐ **Conference** **November 3 - 5, 2025**	**2.395 €**	**2.795 €**
	2'600 $	**3'000 $**

E-Mail

The early bird discount is valid until 5th September 2025, after which the normal prices apply.

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