MAWA EVENTS

Address: No. 857, Block A2. Leisure Commerce Square - No 9., 46150 Petaling Jaya, Selangor, Malaysia

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PHARMACOVIGILANCE (PV) & E-CTD

""Ensuring Drug Safety and Regulatory Compliance Through Vigilance and Digital Submissions""

Schedule

Date	Venue	Fees
18 – 19 Feb 2026	Manama, Bahrain	USD 1995 per delegate
04 – 05 Mar 2026	Doha, Qatar	USD 1995 per delegate
15 – 16 Apr 2026	Dubai, UAE	USD 1995 per delegate

► **Available delivery methods:** Face-to-Face & Online Training

Introduction

Pharmacovigilance plays a critical role in ensuring the safety and efficacy of medicinal products throughout their lifecycle. Coupled with the implementation of the electronic Common Technical Document (eCTD), regulatory compliance and data submission efficiency are becoming increasingly essential in the global pharmaceutical landscape.

This two-day training course provides participants with comprehensive knowledge of PV systems, adverse event reporting, signal detection, and the structure and submission of eCTD dossiers. Ideal for professionals in regulatory affairs, drug safety, and quality management, the course bridges the gap between scientific vigilance and regulatory technology.

Objectives

By the end of this course, participants will be able to:

- Understand the principles and scope of pharmacovigilance in drug lifecycle management
- Establish effective systems for adverse event reporting and safety data management
- Identify key regulatory requirements and best practices for eCTD submissions
- Interpret and compile safety-related documents for regulatory authorities
- Align internal safety protocols with global PV and electronic submission standards

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Why Attend

- Strengthen regulatory compliance and avoid submission delays or rejections
- Learn how to manage post-marketing safety responsibilities effectively
- Understand how eCTD impacts global regulatory interactions and approvals
- Improve pharmacovigilance system design and safety risk communication
- Gain practical knowledge from real-world PV and eCTD implementation cases

Target Audience

This program is designed for:

- Pharmacovigilance and drug safety officers
- Regulatory affairs professionals and submission managers
- Quality assurance and compliance personnel
- Clinical research associates and medical writers
- Healthcare professionals involved in adverse event tracking

Individual Benefits

Key competencies that will be developed include:

- PV process setup and post-market safety monitoring
- Understanding MedDRA, ICH, EMA, and FDA PV regulations
- Compilation and submission of compliant eCTD dossiers
- Risk assessment and benefit-risk communication
- Use of PV software tools and databases

Organizational Benefits

Upon completing the training course, participants will demonstrate:

- Improved safety profile management of pharmaceutical products
- Stronger internal PV systems and regulatory readiness
- Enhanced global submission success via structured eCTD planning
- Better cross-functional collaboration between PV, QA, and regulatory departments
- Reduced compliance risks and enhanced trust with health authorities

Instructional Methodology

The course follows a blended learning approach combining theory with practice:

- Strategy Briefings – Overview of PV systems, safety reporting, and eCTD structure
- Case Studies – Analysis of real-world safety incidents and regulatory feedback
- Workshops – Adverse event assessment, safety narrative writing, and eCTD validation
- Peer Exchange – Group discussions on inspection readiness and global PV standards
- Tools – Templates for DSURs, PSURs, ICSRs, and eCTD compilation

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Course Outline

Detailed 2-Day Course Outline

Training Hours: 07:30 AM – 3:30 PM **Daily Format:** 3–4 Learning Modules | Coffee breaks: 09:30 & 11:15 | Lunch Buffet: 01:00 – 02:00

Day 1: Fundamentals of Pharmacovigilance (PV)

- Module 1: Introduction to Pharmacovigilance (07:30 – 09:30) • Definitions, objectives, and regulatory scope of PV • Lifecycle approach: clinical trial vs post-marketing surveillance • Roles and responsibilities of a PV system
- Module 2: Adverse Event Reporting and ICSR Management (09:45 – 11:15) • Types of safety reports: spontaneous, solicited, literature • ICSR creation, MedDRA coding, and reporting timelines • Systems: EudraVigilance, FDA FAERS, WHO Vigibase
- Module 3: Signal Detection and Risk Management (11:30 – 01:00) • Signal vs. noise in safety data • Risk Management Plans (RMPs) and REMS • Tools and algorithms for signal detection
- Module 4: Workshop – Case Evaluation of a Suspected ADR (02:00 – 03:30) • Participants assess and document an adverse drug reaction case

Day 2: eCTD Framework and Regulatory Compliance

- Module 1: Overview of eCTD Structure and Modules (07:30 – 09:30) • Understanding CTD vs eCTD • Module 1–5 structure: administrative, clinical, nonclinical, quality • Regional specifications and harmonization
- Module 2: eCTD Lifecycle Management and Submissions (09:45 – 11:15) • Initial submission, maintenance, and tracking • Software and validation tools • Common errors and corrective actions
- Module 3: Linking PV and eCTD for Safety Reporting (11:30 – 01:00) • Integration of PSURs, DSURs, RMPs, and narratives • Data management for submission-ready formats • Preparing for regulatory inspections
- Module 4: Final Review and Action Planning (02:00 – 03:30) • Recap of PV and eCTD tools and workflows • Implementation planning and Q&A • Certificate distribution

Certification

Participants will receive a Certificate of Completion in Pharmacovigilance (PV) & e-CTD, confirming their practical knowledge in safety surveillance and digital regulatory submission systems essential to pharmaceutical compliance and public health protection.

Why Choose MAWA Events

- **Global Expertise:** More than 17 years of experience in professional training and consulting.
- **Industry-Leading Faculty:** Courses delivered by seasoned professionals with hands-on experience.
- **Practical Insights:** Learn to turn theory into actionable strategies for real-world business impact.
- **Client-Focused Solutions:** Customized programs designed to achieve your organisation’s unique goals.

In-House / Customized Training Interested in running this course for your team? Please contact us:	TEL: **+601116373203**	EMAIL: **info@mawaevents.net**