



Presented by  
Management Forum

# Demystifying European Post-Marketing Pharmacovigilance

3-7 November 2025

This course provides an overview for senior managers of the key post-market pharmacovigilance activities required to further understand the 2012 EU legislation that has undergone over 20 updates in the last 10 years.



**Format:**  
Live online



**CPD:**  
18 hours for your records



Certificate of completion

# Course overview

**This course provides a comprehensive overview for senior managers of the key post-market pharmacovigilance activities required to further understand the 2012 EU legislation that has undergone over 20 updates in the last 10 years.**

The course intends to show how the safety of products is managed at the regulatory authority level, the interactions with regulatory bodies and pharma, and the internal pharma processes in managing the safety of the company products. From receiving safety cases and information to signal analysis and safety communication, all of this is viewed from a practical point of view for compliance and Key Performance Indicators (KPIs).

The European Medicines Agency (EMA) and the Pharmacovigilance Risk Assessment Committee (PRAC) deliberations and the UK Brexit implications will be discussed.

## Benefits of attending

- **Explore** how the safety of products is managed at the regulatory authority level, the interactions with regulatory bodies and pharma
- **Learn** the internal pharma processes in managing the safety of the company products from receiving safety cases/information, all the way through to signal analysis and safety communication
- **Discuss** The European Medicines Agency (EMA) and the Pharmacovigilance Risk Assessment Committee (PRAC) deliberations and Brexit implications

## Who should attend?

This three-day course is intended for senior management professionals from European and US pharmaceutical companies, who need to understand EU Pharmacovigilance. It will be particularly beneficial for those working in allied technical areas (regulatory, clinical, QA, and auditing) who require an overview of key pharmacovigilance activities and also need to understand the many complexities of EU pharmacovigilance, including the UK Brexit implications.

All of these activities are discussed in relation to Quality Management Systems (QMS), audits and inspections.

# Programme

## Day 1

### An introduction to the new PV structure

- The new modules
- The interaction of the modules
- The EU modules and ICH

### Quality Management Systems (QMS)

- Quality control, quality assurance, and quality management
- Quality management of PV systems
- The QP PV and quality management
- Quality & training
- QA & quality management & internal audits

### The pharmacovigilance systems master file (PSMF)

- The content of the PV master file
- Licence submissions and the PV master file
- The QP PV and the PV master file
- Control/management of the PV master file
- The PSMF/annexes and regulatory inspections

## Day 2

### Pharmacovigilance audits

- The purpose of company audits
- Audit scheduling and risk assessments
- Audit outputs and findings
- Audit findings and their corrections – root cause analysis, corrective action plans, completion and re-audits/scheduling

### Adverse reaction reporting – part 1

- Definitions
- Special situations
- IMEs and DMES
- Triage – seriousness
- Expectedness and causality
- Expedited reporting (including country specific v EMA)

### Adverse reaction reporting – part 2

- Electronic ADR reporting local & international
- Follow up of cases
- ICH E2D – post marketing safety
- Literature ADR reporting
- Case closure

## Day 3

### PBRERs

- ICH E2F & ICH E2C (R2) – DSURs & PSURs/PBRERs
- Objectives of the PSURs
- Risk benefit analyses in PSURs
- The format of the PSUR
- Mapping signals and risks to the PSUR

### Post-authorisation safety studies (PASS)

- The need for PASS
- The design of the PASS
- Results from the PASS & RMPs
- Post-authorisation efficacy studies

### Additional monitoring

- The purpose of additional monitoring for products
- What needs to be done?
- Mandatory & optional aspects of additional monitoring
- The role of the MAH in additional monitoring

## Day 4

### Urgent safety restrictions and safety communications

- Safety communications to the regulatory authorities
- Process for urgent safety restrictions
- What safety communication and where
- Approval and monitoring of safety communications

### The EU QP PV and Local (National) QP PVs

- The roles and responsibilities of the EU QP PV
- Knowledge of the EU QP PV
- The EU QP PV and regulatory inspections
- The EU QP PV & local (QP PVs/responsible person)
- Brexit – The UK QP PV

### Pharmacovigilance inspections

- The purpose of the inspection
- Types of inspection
- Inspection findings
- Re-inspections

## Day 5

### Risk management plans (RMPs)

- ICH E2E – pharmacovigilance planning
- The RMP purpose in Europe
- The RMP format – generic products v innovator
- Updating the RMP
- RMPs & REMs

### Risk minimisation (RM) measures and tools

- Risk minimisation measures
- Educational Tools
- Controlled access programmes
- Other RM techniques

### Signals and their management

- What is a signal?
- Signal scheduling
- Signal validation
- Signal analysis and prioritisation
- Signal assessment
- EVDAS and signalling
- Actions to be taken

# Presenter



## **Graeme Ladds**

Graeme Ladds, Director of PharSafer, has over 30 years' experience working in the pharmaceutical industry. Having started his career at Ashbourne Pharmaceuticals in 1989 as Head of Drug Safety & Medical Information, he went on to become Head of Global Pharmacovigilance at Shire Pharmaceuticals. He then set up his consultancy and specialist CRO company, PharSafer Associates Ltd, where he has been involved in establishing pharmacovigilance in companies, performing audits across Europe and the USA, SOP writing, acting as QP for companies, and helping with regulatory inspections.

# Course date

**3-7 November 2025**

**Live online**

13:00-16:55 **UK (London)** (UTC+00)

Course code 15031

GBP **1,599** ~~1,899~~

EUR **2,239** ~~2,659~~

USD **2,571** ~~3,039~~

**Until 29 Sep**

## How to book



**Online:**

[ipi.academy/2624](https://ipi.academy/2624)

Alternatively contact us to book, or if you have any queries:



**Email:**

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**Phone:**

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## Discounts

- Booking more than one delegate on any one date qualifies for a **30% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

## Further information

### Fee

The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

### Please note

IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

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The rest of our terms, the event cancellation policy and the terms and conditions are on our website, please visit [ipi.academy/content/terms-and-conditions](https://ipi.academy/content/terms-and-conditions)

# Reviews



**Graeme was a comfortable speaker that was open to questions throughout his presentations which was very positive.**



**Robin van Osch**

Junior pharmacovigilance officer

Interdos

Jul 15 2024

## Run this programme in-house for your whole team

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