IPI Academy

MANAGEMENT forum

Presented by
Management Forum

European Post-Marketing Pharmacovigilance

14-16 July 2025
+ 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

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

Pharmacovigilance inspections

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

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

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

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

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

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

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

Risk minimisation (RM) measures and tools

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

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

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 dates

14-16 July 2025	**Live online** 09:00-17:00 **UK (London)** (UTC+01) *Course code 14833*	GBP **1,899** EUR **2,659** USD **3,039**
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

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

Email:
info@ipiacademy.com

Phone:
+44 (0)20 7749 4749

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.

Terms and conditions
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit 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

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:

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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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