IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Clinical & Post-Marketing Safety

17-18 September 2025
+ 20-21 January 2026, 4-5 May 2026

This two-day course covers international standards for clinical and post-marketing drug safety, including ICH guidelines, adverse event reporting, signal detection, and risk management strategies.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

This two-day course on provides a comprehensive overview of international standards and best practices in drug safety monitoring. Day 1 focuses on Clinical Safety, covering pre-clinical safety, ICH E guidelines for safety data capture, adverse event reporting, and risk management strategies in clinical trials. Participants will gain insights into signal detection, investigator brochure requirements, and regulatory obligations across trial phases. Day 2 shifts to Post-Marketing Safety, addressing ICH E2D standards, post-marketing vigilance, safety information updates, and risk mitigation strategies.

Benefits of attending

- **Gain** a comprehensive understanding of clinical and post-marketing drug safety regulations
- **Learn** ICH guidelines for safety data capture, adverse event reporting, and risk management
- **Enhance** your ability to detect safety signals in clinical trials and post-marketing surveillance
- **Understand** regulatory obligations across different trial phases and post-authorisation
- **Improve** your skills in developing risk management plans and mitigation strategies
- **Stay** updated on global pharmacovigilance standards and best practices

Who should attend?

Professionals working within these industries, who want a comprehensive introduction, will benefit from this engaging course:

- Clinical
- Pharmacovigilance
- Regulatory

Programme

Day 1

Clinical safety – international standards (ICH)

- Pre-clinical safety – the precursor to human safety
- ICH E Standards for safety data capture and reporting
- Phases I–III for safety monitoring
- Phase IV safety obligations

ICH EA individual (serious) adverse event data capture and reporting

- ICH E2A – definitions of (serious) adverse events
- What data needs to be captured
- Safety data reporting requirements (expedited)
- National variations on ICH E2A

Safety information and the Investigator Brochure (IB)

- ICH E6 (R3) and the IB
- What safety information is required in the IB
- Safety updates to the IB
- Safety expectedness and the IB

Safety information and the protocol (ICH E6 R3)

- What safety information needs inclusion in the protocol
- Special product specific ADRs
- Pregnancy exposure safety information
- Special safety information in clinical trials

Signal detection in clinical trials

- Definitions of what is a signal
- Regulatory requirements for safety signal analysis
- The role of the IDMC/DSMB
- Class related signals

Risk Management Plans (RMPs) and mitigation strategies from clinical trials

- The Risk Management Plan (RMP)
- Risk minimisation activities
- The post-authorisation safety/efficacy study
- Monitoring for 'special' ADRs

Day 2

Post-marketing safety – International Standards (ICH)

- Post-marketing safety reporting – the precursor to human safety
- ICH E standards for safety data capture and reporting (ICH E2D (R1))
- Early post-marketing vigilance standards
- Phase IV safety obligations – monitoring and reporting

ICH E2D individual (serious) adverse event data capture and reporting

- ICH E2D – definitions of (serious) adverse events
- What data needs to be captured
- Safety data reporting requirements (expedited)
- National variations on ICH E2D (serious and non-serious case reporting)

Safety information and the Summary of Product Characteristics (SPC)/product monograph

- Expectedness vs. listedness – the difference?
- The SPC vs. Core Safety Information (CSI)
- Safety updates to the SPC for innovator and generic products
- Safety expectedness and the SPC/CSI

Safety information and post-marketing studies

- The Post-Authorisation Safety Study (PASS)
- The Periodic Benefit-Risk Evaluation Report (PBRER) (ICH E2C (R3))
- Special product specific ADRs
- Pregnancy exposure safety information
- Special safety information in clinical trials

Signal detection in post-marketing products

- Definitions of what is a signal?
- Regulatory requirements for safety signal analysis for post-marketing
- The role of the regulators and Pharmacovigilance Risk Assessment Committee (PRAC)
- Class related signals

Risk Management Plans (RMPs) and mitigations strategies from post-marketing

- The Risk Management Plan (RMP) and updates
- Risk minimisation activities and updates
- The post-authorisation safety/efficacy Study – filling in the gaps
- Monitoring for 'special' ADRs – where do updates appear?

Presenter

Graeme Ladds

Graeme is Director of PharSafer and has over 30 years' experience working in the pharmaceutical industry, having started his career at Ashbourne Pharmaceuticals as Head of Drug Safety and Medical Information. Graham has a wealth of experience establishing pharmacovigilance within companies.

Course dates

17-18 September 2025	**Live online** 09:00-17:00 **UK (London)** (UTC+01) *Course code 15678*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 13 Aug**
20-21 January 2026	**Live online** 09:00-17:00 **UK (London)** (UTC+00) *Course code 15679*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 16 Dec**
4-5 May 2026	**Live online** 09:00-17:00 **UK (London)** (UTC+01) *Course code 15680*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 30 Mar**

How to book

Online:
ipi.academy/3274

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

Email:
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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.

Terms and conditions
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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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