IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Advanced Pharmacovigilance: From Performing Successful Due Diligence to Benefit-Risk Assessments – What to Consider

6-10 October 2025

This course will be of maximum benefit to those drug safety professionals who are working both in the clinical and post-marketing safety arena including QA for auditing.

Format:
Live online

CPD:
18 hours for your records

Certificate of completion

Course overview

Pharmacovigilance has undergone rapid regulatory change in recent years, which has resulted in a complex range of safety and risk assessment activities to perform. This three-day course is designed for those with at least two years' knowledge in drug safety and will provide a comprehensive, yet practical assessment of the main regulations required to produce a compliant reporting company.

Key topics to be addressed:

- Audits and expectations – risk-based inspections
- Compliance and drug safety
- Overview of the PSMF in the EU
- Product safety reviews – purpose and function (incorporating the latest EU signal analysis requirements)
- Safety reporting in licensing agreements
- Developing company core safety information (CCSI) – CIOMS III
- PSURs – timing, content and the DSUR and the latest ICH E2C (2nd revision requirements)
- Implications for safety reporting in global clinical trials
- Risk-benefit determinations
- Risk management plans (RMPs)

Benefits of attending

- **Expand** your global safety knowledge
- **Enhance** your team's capabilities and compliance in both the regulations and your company's expectations
- **Help** ensure you build and maintain a quality pharmacovigilance department ready for any pharmacovigilance inspection
- **Participate** in group workshop sessions and discuss how to apply the legislation to ensure compliance, especially to satisfy regulatory inspections

Who should attend?

This course would be of maximum benefit to those safety professionals who are working both in the clinical and post–marketing safety arena including QA for auditing. The course covers very diverse activities within the safety department and would be advantageous to those who have either multifunction responsibilities or medical directors who manage teams in the various disciplines.

Programme

Day 1

Due diligence

- Due diligence on products/companies (partners and acquisitions)
- Due diligence involvement – team composition
- Safety information requirements for due diligence
- Review of safety data (clinical and post-marketing)
- Defining risk in due diligence appraisals

Training for drug safety reporting duties

- Regulations concerning safety training
- Who trains whom and when?
- Training versus job description
- Training records, maintenance and updates
- Role of QA and HR in training

Audits and expectations

- Regulatory expectations in pharmacovigilance audits (risk-based inspections)
- Preparation for the audit
- Records to be available at the audit
- Audit findings/recommendations

Day 2

Compliance and drug safety

- Basic principles – what will the regulators want to see?
- Measuring compliance
- Quality versus quantity in safety reports
- Future aspects in ensuring efficient compliance
- Quality management under the new EU legislation

The PSMF

- The PSMF – purpose and maintenance
- The PSMF annexes
- The PSMF and audits

Interactive exercise: The requirements for a safety department

Product safety reviews – purpose and function

- The Safety Review Committee (SRC)
- What to look for in signal evaluation under latest EU guidance
- Timings for safety review in clinical and post-marketed products
- Record keeping for safety review meetings
- Serious safety findings – crisis management following new safety findings

Day 3

Interactive exercise: designing the requirements for a safety review group

Safety reporting in licensing agreements

- What types of licensing agreements exist?
- What are the EU and FDA regulations concerning licensing agreements?
- Audits of pharmacovigilance capabilities in licensing partners
- What agreements need to be in place for safety reporting?
- Safety reporting agreements – what needs to be covered?
- Monitoring safety agreements – what happens if it goes wrong?

Developing CCSI – CIOMS III

- CIOMS III and CCSI
- Developmental core safety information (DCSI)
- How to determine what to include and what to exclude in DCSI/CCSI
- Are there differences in EU and FDA?
- Maintenance and development of CCSI

Day 4

Interactive exercise: should new safety data from a clinical trial be put into core safety information?

PSURs and the revisions in ICH E2C

- Timing for PSURs
- PSUR content and latest format
- Late breaking information and PSUR extensions
- The DSUR

The EU Clinical Trials Directive

- The principles of the Directive
- Implications for safety reporting in global clinical trials
- The SUSAR database
- The EUDRACT database
- The new EU clinical trial regulation

Risk-benefit determinations

- Definitions of risk-benefit – FDA and EU perspective
- Risk-benefit assessments – who does this and where does the information go?
- Safety assessments and risk-benefit – frequency and reporting
- Changes in risk-benefit – how to manage and review existing profiles

Programme

Day 5

Interactive exercise: reviewing the safety and risk-benefit of a product

RMPs

- Purpose
- Content
- Monitoring and updating the RMP
- Reporting the RMP

Crisis management within drug safety

- Regulations and guidelines in connection with serious safety issues
- What determines a crisis?
- Communications to regulators – what is required?
- Communications within the company
- What happens next?

Interactive exercise: deciding how to handle a major crisis within the company

Delegates will be split into groups and present what they need to have in place in order to effectively manage the crisis and look to its resolution.

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

6-10 October 2025	**Live online** 13:00-17:15 **UK (London)** (UTC+01) *Course code 15137*	GBP **1,599** ~~1,899~~ EUR **2,239** ~~2,659~~ USD **2,571** ~~3,039~~ **Until 01 Sep**

How to book

Online:
ipi.academy/1475

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

★★★★★

Overall, 5* - Excellent. I learnt a lot of things in detail. Now happily I can implement those with my current job. All the sessions very helpful for me. Excellent speaker, explained very well and in detail for every question.

Vijaya Laxmi-Tunakala
QA Officer
Pharmacare Premium Ltd
Mar 24 2025

★★★★★

EXCELLENT - worth the time and money. I hoped to gain additional knowledge in Pharmacovigilance/show me areas where I may be lacking. I did not want the training to be a waste of time out of the office...[it was] definitely not — I would highly recommend the speaker and the course. 5/5 overall.

Nicky Höll
Pharmacovigilance Manager
Eurolab (Pty) Ltd
Mar 24 2025

★★★★★

Learned a lot! The presenter was definitely a subject matter expert who was able to answer my questions immediately. He didn't just read from the slides and was able to provide examples of concepts using real-life experience. I found the sections on the PSMF and Benefit vs. Risk particular helpful.

Scott Aveni
Corp R&D QA, PV US Compliance Mgr.
Chiesi USA
Sep 18 2024

★★★★☆

The speaker demonstrated a deep understanding of pharmacovigilance and regulatory processes, providing valuable insights into the complexities of signal detection and risk management [with] real-world examples and case studies that were directly applicable to my work in drug safety and pharmacovigilance.

Intan Soleha
Senior Executive
PHARMANIAGA BERHAD
Sep 18 2024

Run this programme in-house for your whole team

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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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