IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Signal Detection and Regulatory Expectations

25-26 February 27
+ 29-30 September 27

This two-day course provides a comprehensive review of signal detection and regulatory expectations, including the newly updated Signal Module IX and the Eudravigilance quantitative signal requirement.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

Increasingly, the most common critical findings in regulatory inspections relate to signal detection and signal management. As regulatory expectations continue to rise, the ability to identify potential safety signals and risks in patients has never been more important. Protecting patients through robust, structured, and compliant methodologies now requires companies to ensure their teams are highly trained, confident, and competent in these essential activities.

This comprehensive course delivers a detailed, practical overview of all key aspects of safety reviews and signal detection within a company. It covers signal evaluation for both innovator and generic products, in line with the updated Module IX (and addendum) signal management requirements, including the critical links to Risk Management Plans (RMPs) / Risk Evaluation and Mitigation Strategies (REMS). The course also addresses benefit–risk determinations and quantitative signal assessments, providing participants with the knowledge needed to meet regulatory expectations with confidence.

To ensure practical understanding and real-world application, examples and interactive exercises are included throughout the course, enabling delegates to strengthen their skills and apply learning directly to their day-to-day roles.

Benefits of attending

- **Clarify** EU/FDA regulatory requirements for signal detection
- **Data** sources used in signal detection and their practical application
- **Learn** to use the EudraVigilance quantitative signal tool, including EVDAS functionalities and outputs
- **Understand** the safety review cycle, meetings, and associated processes
- **Discuss** safety communication, including CCSI/DCSI and labelling requirements
- **Processes** for urgent safety restrictions and their implementation
- **Gain** a clear understanding of risk–benefit analysis, assessments, and outcomes
- **Understand** how signals influence RMPs/REMs and PASS
- **Practical** examples and scenarios to reinforce learning through hands-on application

Who should attend

This course is ideal for professionals working in:

- Drug Safety / Pharmacovigilance teams
- EU QP PV/Heads of Pharmacovigilance
- RMP Personnel
- Periodic Report Writers
- Regulatory affairs staff responsible for product labelling updates
- Personnel involved in the preparation of CCSI / DCSI documents

It is designed for anyone who needs practical knowledge of signal detection, safety reviews, and risk management processes.

Programme

Day 1

An introduction to safety signals

- History of safety signals
- The nature of safety signals
- The definition of safety signals
- Safety sources for signal detection

Causality and signal detection

- Causality assessments for signal review
- Data quality in safety assessments
- Causality versus incidence (DMEs and IMEs)
- Generic and innovator products
- Regulatory Authorities and signals

The safety review meeting and process

- Setting up a safety review
- Risk determinations for safety review signal trackers purpose
- Information and templates
- Logistical safety and product safety
- Information from safety reviews

Safety assessments life cycle

- Pre-clinical safety
- Clinical safety
- Class-related safety issues
- Post-marketing safety
- Product suspensions/withdrawals – when and how

The regulatory requirements for signal detection – Module IX

- The frequency of safety reviews (risk assessment)
- The EU and US signal detection requirements
- Signal detection and benefit-risk assessments
- The regulators and signals

The signal review cycle

- Safety profiling
- Signal detection, validation, confirmation
- Analysis and prioritisation, assessment
- Open and Closed signals
- Recommendation for action

Day 2

Qualitative signal detections

- Standard MedDRA queries (SMQs) and signal detection
- ICSRs and case quality
- Follow-up methodology and regulatory requirement
- Events of special interest

Signals and their discussion

- Signals and DSURs
- Signals and PSURs/PBRERs
- Signals and risk management plans/REMs and minimisation
- Signals and labelling

Safety communication

- The CCSI/DCSI and labelling
- Triaging for safety amendments
- Emerging safety issues
- Urgent safety restrictions
- Product suspension and withdrawal

Quantitative signal analysis

- Signal detection methodologies
- Background – why quantitative signal detection?
- Measures of disproportionality (PRR, ROR, MGPS, BCPNN)
- Regulatory and industry activity (including EudraVigilance)

EVDAS and the EU

- The PRAC and signals
- The EVDAS system
- Signals arising from EVDAS

Risk-benefit analysis

- Calculating the extent of benefit by indication
- Identifying significant product risks
- Benefit-risk assessments
- Benefit-risk outcomes

Presenter



Graeme Ladds

Graeme Ladds, Director of PharSafer, has over 30 years' experience in the pharmaceutical industry. He began his career in 1989 at Ashbourne Pharmaceuticals as Head of Drug Safety & Medical Information, before going on to become Head of Global Pharmacovigilance at Shire Pharmaceuticals.

He later founded his consultancy and specialist CRO, PharSafer Associates Ltd, where he has supported companies in establishing pharmacovigilance systems, conducting audits across Europe and the USA, developing SOPs, acting as a QP, and supporting regulatory inspections.

Since 1994, Graeme has also been involved in the monitoring of medical devices, including drug–device combinations, structural devices and electrical medical devices. His experience spans clinical trials and global device vigilance, alongside pharmacovigilance activities across both clinical development and post-marketing phases.

Course dates

25-26 February 27	**Live online** 09:00-16:30 **UK (London)** (UTC+00) *Course code 16990*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 31 Dec**
29-30 September 27	**Live online** 09:00-16:30 **UK (London)** (UTC+01) *Course code 17368*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 04 Aug**

How to book

Online:
ipi.academy/2122

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

★★★★★

It was well organized with relevant handouts and good suggestions about where to find out out more. [Speaker] was very knowledgeable and there was a lot of information. He gave good answers to questions.

Fiona Broderick
Principal Medical Writer
Norgine
Jul 7 2025

★★★★★

Excellent. I believe I accomplished what I wanted to gain from this course: to learn more about the relevance of signal detection and the process of conducting signal detection. Very proficient speaker and knowledgeable about the topic.

Esme Venter
Principal Medical Reviewer
MMS Affiliate SA (Pty) Ltd
Jul 7 2025

★★★★☆

Very good. Excellent in-depth overview of PV and signal detection/management concepts.

Kristen Mandello
Associate Director
Zoetis
Jul 7 2025

★★★★☆

Very detailed and informative.

Antonella Fusco
PV Medical Function
ALFASIGMA SPA
Jul 1 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:



ALEKSANDRA BEER
Tel: +44 (0)20 7749 4749
Email:
inhouse@ipiacademy.com



YESIM NURKO
Tel: +44 (0)20 7749 4749
Email:
inhouse@ipiacademy.com



Harry ALTAMONT
Tel: +44 (0)20 7749 4749
Email:
inhouse@ipiacademy.com

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.

10-12 Rivington Street
London EC2A 3DU

ipi.academy
Tel: +44 (0)20 7749 4749
Email: info@ipiacademy.com