IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Signal Detection and Regulatory Expectations

18-21 November 2025
+ 2-3 February 2026, 30 September-1 October 2026

This two-day programme will give you a comprehensive review of signal detection and regulatory expectations including the new updated Signal Module IX and 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 are being given for signal detection and signal management – so the need to identify potential signals and risks in patients has never been greater. The protection of patients through robust and clear methodologies for signal detection amidst the ever-increasing regulations requires companies to have trained and competent staff to perform such activities.

This course will provide a detailed overview of all aspects of safety reviews and signal detection within a company and will cover signal evaluation for both innovator and generic products under the updated Module IX (and addendum) signal management and the links to RMP/REMs; Benefit-Risk determinations and quantitative signal assessments.

Practical examples and exercises are performed throughout the course.

Benefits of attending

- **Clarify** the EU/FDA regulatory requirements for signal detection and data sources to be used in signal detection
- **Learn** to understand the EudraVigilance quantitative signal tool utilising the EVDAS functionalities and outputs
- **Understand** the safety review cycle and the safety review meeting and process
- **Discuss** safety communication – the CCSI/SCSI and labelling
- **Explore** processes for urgent safety restrictions
- **Gain** a better understanding of risk-benefit analysis – benefit-risk assessments and benefit-risk outcomes
- **Know** the influence of signals on RMPs/REMs and PASS
- **Investigate** practical examples and scenarios for delegates to consider and work on

Who should attend?

This course will be of interest to all those working in drug safety/pharmacovigilance as well as regulatory personnel responsible for amending the labelling for products and for the production of the CCSI/DCSI.

Programme

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

The safety review meeting and process

- Setting up a safety review
- Risk determinations for safety review signal trackers
- 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

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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
- Recommendation for action

Quantitative and qualitative signal detections

- Standard MedDRA queries (SMQs) and signal detection
- ICSRs and case quality
- Follow-up methodology and regulatory requirements
- 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 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

18-21 November 2025	**Live online** 13:30-17:00 **UK (London)** (UTC+00) *Course code 15063*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 14 Oct**
2-3 February 2026	**Live online** 09:00-16:30 **UK (London)** (UTC+00) *Course code 16208*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 29 Dec**
30 September-1 October 2026	**Live online** 09:00-16:30 **UK (London)** (UTC+01) *Course code 16723*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 26 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

★★★★★

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 detailed and informative.

Antonella Fusco
PV Medical Function
ALFASIGMA SPA
Jul 1 2024

★★★★☆

It was excellent.

María Jesús Bermejo San Román
Pharma Mar, S.A.
Jul 1 2024

★★★★☆

A good presentation with lot of examples. The speaker is well versed with the topic and pharmacovigilance practices. All other non-signal questions were also answered. Appreciate that

Sanam Chandwani
Manager Aggregate reports
Accord Healthcare
Mar 18 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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