IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Literature Searching in Drug Safety

13-14 May 27
+ 9-10 November 27

This two-day course offers a thorough understanding of literature searching in drug safety, covering regulatory requirements, search criteria, and the interpretation of safety data, while also providing practical assessments to apply knowledge to real-world pharmacovigilance cases.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

This comprehensive two-day course provides an in-depth understanding of literature searching in drug safety, focusing on regulatory requirements, literature search criteria, and the interpretation of safety data from published sources. Participants will explore best practices for conducting literature searches, identifying relevant safety information, and prioritising articles for review. Practical assessments will enable attendees to apply their knowledge to real-world case studies, ensuring they are equipped with the necessary skills to effectively manage literature searches in pharmacovigilance.

Benefits of attending

- **Gain** a clear understanding of global and local literature searching regulatory requirements
- **Learn** how assessments help refine literature evaluation and reporting abilities
- **Explore** how to assess safety data to identify potential risks and compliance needs
- **Develop** critical analysis skills for interpreting safety data from literature
- **Discover** how to effectively manage literature searches within pharmacovigilance processes

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

The regulations concerning literature searchin

- What needs to be searched
- Individual safety data and 'group' data
- The literature search engine requirements – regulatory expectations
- Local literature searching versus global – regulatory expectations

The literature search criteria

- Regulatory expectations
- Setting up the literature search
- Excipients and literature searching
- Literature search 'hits' and reviews

What literature articles need to be reviewed

- Individual Case Safety Reports (ICSRs)
- Medical literature monitoring (MLMs)
- Meta-analyses
- Class effect reports
- Clinical studies
- Pharmacoepidemiological studies
- Foreign reports in the literature involving the active ingredient

Prioritisation of literature articles

- ICSRs including abstracts
- Study reports – clinical studies
- Pharmacoepidemiological studies
- Off-label studies

Literature article reviews

- Literature articles and ICSRs
- Literature articles and Periodic Benefit-Risk Evaluation Report (PBRERs)
- Literature articles in signal detection
- Literature articles and 'special situations'

Day 2

Practical assessment of literature article and ICSRs

- What needs to happen with a literature article report that contains an ICSR
- What needs to happen with the article, timelines and reporting

Practical assessment of a pre-clinical finding in the literature

- Review a literature article containing information from a pre-clinical study in the literature that contains safety information that is not included in the SPC/Product Monograph and what to do next
- Delegates will be asked what needs to be done with such an article

Practical assessment of a clinical study

- Delegates will be given a clinical study from the literature conducted by academics for an off-label indication for the company product
- Delegates will be asked what needs to happen with such a report

Practical assessment of a study involving the company

- Delegates will look at a study involving the company product and asked whether and what should be looked at in the study and where such information should be discussed and reported

Practical assessment of a pharmacoepidemiological study

- Delegates will be provided with a pharmacoepidemiological study involving the company product
- They will be asked to interpret the information, including what needs to happen next and what if any influence this would have on current labelling or signalling

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

13-14 May 27	**Live online** 09:00-17:00 **UK (London)** (UTC+01) *Course code 17184*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 18 Mar**
9-10 November 27	**Live online** 09:00-17:00 **UK (London)** (UTC+00) *Course code 17469*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 14 Sep**

How to book

Online:
ipi.academy/3271

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

★★★★★

I appreciate his approach to PV, very accessible when we have questions. His large experience helps to provide a good oversight.

Manon Schönholzer
Chargee Pharmacovigilance
CIS Bio international
Nov 10 2026

★★★★☆

Excellent presentation delivered by a by a knowledgeable speaker with a lot of practical knowledge!

Nika Božić
Regulatory Specialist and PV Associate
Stada d.o.o.
Sep 16 2025

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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