IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Pharmacovigilance: An Overview of Drug Safety from Safety Collection to Regulatory Inspection

8-9 September 2025

A practical guide to understanding the role of pharmacovigilance.

Format:
Live online

CPD:
6 hours for your records

Certificate of completion

Course overview

Pharmacovigilance has undergone rapid regulatory change in recent years and become one of the most demanding aspects of the pharmaceutical industry to both understand and comply with. There are many requirements and duties for companies to perform regarding the safety of their products to satisfy regulatory demands, and sanctions for non-compliance can be severe.

EU pharmacovigilance legislation requires companies to train all staff, including those not working directly in pharmacovigilance, and this invaluable one-day course will help you meet that requirement with a concise overview of the pharmacovigilance function and current regulatory requirements.

Benefits of attending

- **Gain** an overview of EU pharmacovigilance
- **Understand** the documentation required by regulatory authorities
- **Clarify** the roles and responsibilities of a licence holder
- **Understand** the role of the Qualified Person for Pharmacovigilance (QPPV)
- **Review** the standard operating procedures (SOPs) in relation to pharmacovigilance

Who should attend?

This course will be relevant for anyone requiring an overview of pharmacovigilance or wishing to consolidate existing knowledge. It will also benefit those working in pharmacovigilance, as well as those who support or interact with pharmacovigilance from areas including medical information, regulatory affairs, clinical, sales and marketing, legal, commercial and quality.

Programme

Day 1

An introduction to EU pharmacovigilance

- Safety report sources
- Safety reporting requirements
- Follow-up of safety reports
- Electronic safety reporting
- Safety file retention

Documentation to be supplied to regulatory authorities

- Individual case safety reports – special situations – EU
- Periodic safety update reports (PBRERs, DSURs, RMPs)
- Answering queries from regulatory authorities
- Updating product labelling – emphasis on safety changes

Department links in the company to pharmacovigilance

- Product quality and pharmacovigilance
- Sales and marketing and pharmacovigilance
- Legal, commercial and pharmacovigilance
- Regulatory and pharmacovigilance
- Medical information and pharmacovigilance

The roles and responsibilities of a licence holder

- Obtaining a licence for a product – the PSMF
- Supporting the licence approval
- Quality management requirements
- Submissions and licence approvals
- Regulatory inspections

Day 2

The role of the QPPV

- Essential attributes of the QPPV
- The duties of the QPPV and what the QPPV must do
- Internal audits of the company pharmacovigilance activities

SOPs in relation to pharmacovigilance

- Why the need for SOPs?
- Critical SOPs
- SOP maintenance
- SOP training
- Who should be trained and in what?

Pharmacovigilance inspections

- Purpose of a regulatory inspection
- Scope of the pharmacovigilance inspection
- Conduct of the pharmacovigilance inspection
- The pharmacovigilance inspection report
- Corrective actions following a pharmacovigilance inspection

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

8-9 September 2025

Live online
13:30-17:00 **UK (London)** (UTC+01)
Course code 14902

GBP **649** ~~749~~
EUR **909** ~~1,049~~
USD **1,043** ~~1,199~~
Until 04 Aug

How to book

Online:
ipi.academy/2241

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

★★★★★

Loved it. Great content, great presenter/instructor. He was engaging and explained things clearly, answering questions along the way. I particularly liked the way he brought the content to life and gave greater insight through sharing examples of his personal experiences. Great course, would recommend.

Kishori Amatya
PV and MI officer
Jenson R+
May 15 2025

★★★★★

Very competent.

Jesper Bergwik
Regulatory Affairs Associate
Bioglan AB
May 15 2025

★★★★☆

An excellent webinar, delivered by a very knowledgeable person in an impactful way by great use of analogies and first hand experiences that brought the learning to life. First experience and a very pleasant one.

Lee Gittings
Country Manager
Biofrontera UK Ltd
May 15 2025

★★★★★

This was a very good course; interesting and relevant content, good presentation and very competent speakers.

Ellinor Eliasson
Senior Quality Consultant
Scandinavian Regulatory Services AB
Jan 29 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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