



*Presented by*  
**Management Forum**

# Pharmacovigilance Aspects of Licensing Agreements

**1-2 December 2025**

This programme will be of interest to all personnel involved in business development and licensing agreements aspects of pharmacovigilance



**Format:**  
Live online



**CPD:**  
6 hours for your records



Certificate of  
completion

# Course overview

**Whilst licensing agreements involving medicines are primarily driven by commercial factors, the successful handling of pharmacovigilance obligations is a critical, but frequently overlooked, consideration.** Negotiating the safety arrangements to ensure regulatory compliance by both partners can be a complex process, which is further compounded by a lack of harmonisation and clarity of the regulations around the world.

This intensive one-day seminar will review the existing global requirements relating to pharmacovigilance in contractual agreements. The emphasis will be on practical advice as to how to remain compliant with the legal obligations and how to satisfy good pharmacovigilance practice and quality management requirements, as well as how to promote harmonious business partnerships.

A practical workshop session will help consolidate the information provided under the guidance of our expert trainers.

## Who should attend?

The programme will be of interest to all personnel involved in business development and licensing agreements, including those working in drug safety and pharmacovigilance, regulatory affairs and drug registration, medical directors, R&D directors and company lawyers.

## Benefits of attending

- **Make sense** of the licensing agreement jungle
- **Ensure** you stay compliant with global pharmacovigilance requirements
- **Understand** what the regulators expect
- **Master** the essentials of licensing agreements – safety and business considerations
- **Consider** the legal status and role of pharmacovigilance licensing agreements
- **Discuss** audit and compliance aspects of third-party agreements

# Programme

## Day 1

### Global regulatory framework

- EU, USA and what ICH says
- How it impacts partnerships
- What the regulators expect
  - From the pharmacovigilance system
  - From the MAH
  - From the MAH's partners

### Best pharmacovigilance practices in licensing agreements

- Types of agreement
- Safety Data Exchange Agreement
- Who is responsible for what?
- Joint handling of pharmacovigilance issues

### Legal aspects

- The legal status and role of pharmacovigilance agreements
- Drafting pharmacovigilance agreements
  - Contract basics, dos and don'ts
  - Terminology, form and content
  - Using templates
- Contractual liability and indemnities
- Amendment and termination of pharmacovigilance agreements

## Day 2

### Audit and compliance aspects of third-party agreements

- Regulatory expectations and inspections
- Which agreements to examine at audit
- What to look for in safety data exchange agreements at pharmacovigilance audit
- Which partners to audit and how
- Measuring partner/other party compliance

### Workshop – practical aspects of licensing agreement

# Presenters



**Joanne Flitcroft**

Joanne Flitcroft is a qualified solicitor with over 22 years' experience. She trained in the City of London and later specialised in pharmacovigilance as part of a FTSE 100 pharmaceutical company's global legal team. Joanne founded Opallios in 2016, a legal consultancy providing advice to companies operating in the life sciences sector. Her clients include pharmaceutical companies, CROs and health communications companies. Joanne is a Non-Executive Director on the Board of the British Society of Gastroenterology, a Governor on the Board of Edge Hill University and a school governor. She has travelled across West Africa in a Ford Fiesta and besides travel, enjoys spending her spare time pursuing her interest in the classics.



**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

**1-2 December 2025**

**Live online**

13:30-16:45 **UK (London)** (UTC+00)

Course code 15099

GBP **649** ~~749~~

EUR **909** ~~1,049~~

USD **1,043** ~~1,199~~

**Until 27 Oct**

## How to book



**Online:**

[ipi.academy/1621](https://ipi.academy/1621)

Alternatively contact us to book, or if you have any queries:



**Email:**

[info@ipiacademy.com](mailto:info@ipiacademy.com)



**Phone:**

[+44 \(0\)20 7749 4749](tel:+442077494749)

## 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 our terms, the event cancellation policy and the terms and conditions are on our website, please visit [ipi.academy/content/terms-and-conditions](https://ipi.academy/content/terms-and-conditions)

# Reviews



**Both speakers were very knowledgeable and approachable for any questions. The solutions provided were helpful on specific scenarios.**



**Heena Murarji**

Global PV Alliance Manager

OTSUKA PHARMACEUTICALS EUROPE LTD

Jul 10 2024



**Excellent content and great detailed presentations.**



**Michele Power**

Global Pharmacovigilance Alliance Manager

Otsuka

Jul 10 2024



**The content, presentation and speaker were very interesting and clear. They will enable me to improve the management and content of the company's vigilance agreements.**



**Diarra Ndour**

Innothera Corporate Services – Groupe Innothera

Nov 27 2024



**It was a very good webinar and a great topic, as I have not seen this topic in webinars before.**



**Dorte Jensen**

QPPV Deputy

2care4 Generics ApS

Mar 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](mailto:inhouse@ipiacademy.com)



**YESIM NURKO**

**Tel:** +44 (0)20 7749 4749

**Email:** [inhouse@ipiacademy.com](mailto: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](http://ipi.academy)

**Tel:** +44 (0)20 7749 4749

**Email:** [info@ipiacademy.com](mailto:info@ipiacademy.com)