IPI Academy

MANAGEMENT forum



*Presented by*
**Management Forum**

# Pharmacovigilance Aspects of Licensing Agreements

**9 December**
+ 30 June 27, 8 December 27

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

**Licensing agreements for medicines may be commercially driven, but overlooking pharmacovigilance obligations can create significant regulatory risk. Ensuring both partners meet their safety responsibilities requires careful negotiation, particularly in a global landscape where regulations often lack harmonisation and clarity. Getting these arrangements right is not just a legal necessity, it is essential for protecting patients and sustaining successful collaborations.**

This intensive one-day course offers a focused exploration of global pharmacovigilance requirements within contractual agreements. It brings the subject to life with practical insights on maintaining compliance with legal obligations, meeting good pharmacovigilance practice and quality management standards, and building strong, cooperative partnerships between organisations.

To reinforce learning, the workshop session allows delegates to apply key concepts in a guided, practical setting, supported by expert trainer, Graeme Ladds, who bring real-world experience to the discussion. By the end of the course, delegates will be better equipped to navigate the complexities of pharmacovigilance in licensing agreements with confidence and clarity.

## Benefits of attending

- **Navigate** the complexity of licensing agreements with greater clarity
- **Stay** compliant with global pharmacovigilance requirements
- **Understand** exactly what regulators expect
- **Grasp** the essentials of licensing agreements, including safety and business considerations
- **Explore** the legal status and role of pharmacovigilance licensing agreements
- **Examine** audit and compliance challenges in third-party agreements

## Who should attend

This course is designed for professionals involved in business development and licensing agreements, including:

- Drug safety and pharmacovigilance specialists
- Regulatory affairs and drug registration professional
- Medical directors
- R&D directors
- Company lawyers

# Programme

**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

**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
- SDEAs and the PSMF

**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 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

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|---|---|---|
| **9 December** | **Live online**<br>09:30-16:30 **UK (London)** (UTC+00)<br>*Course code 16584* | GBP **749**<br>EUR **1,049**<br>USD **1,199** |
| **30 June 27** | **Live online**<br>09:30-16:30 **UK (London)** (UTC+01)<br>*Course code 17263* | GBP **649** ~~749~~<br>EUR **909** ~~1,049~~<br>USD **1,043** ~~1,199~~<br>**Until 05 May** |
| **8 December 27** | **Live online**<br>09:30-16:30 **UK (London)** (UTC+00)<br>*Course code 17671* | GBP **649** ~~749~~<br>EUR **909** ~~1,049~~<br>USD **1,043** ~~1,199~~<br>**Until 13 Oct** |

## How to book

**Online:**
ipi.academy/1621

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

★★★★☆

**Overall, this training increased my confidence in managing SDEAs. This was confirmed by the workshop at the end.**

**Danie Moubarak**
Global Safety Officer S1
NOOUS
Jun 25 2026

★★★★★

**Excellent and would recommend.**

**Sejal Mistry**
PV International Specialist
Kedrion Biopharma
Jul 1 2025

★★★★★

**Very good.**

**Rosa Mezzadri**
GPO Specialist Contract Manager
Chiesi Farmaceutici S.p.A
Jul 1 2025

★★★★☆

**I enjoyed the training, I learnt a lot. Very happy with the speakers**

**Nicky Höll**
Pharmacovigilance Manager
Eurolab (Pty) Ltd
Dec 1 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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