IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Pharmacovigilance Aspects of Licensing Agreements

1 July 2025
+ 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

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
  - Usingtemplates
- 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

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 dates

1 July 2025	**Live online** 09:30-16:30 **UK (London)** (UTC+01) *Course code 14818*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 27 May**
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

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 **15% 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

★★★★★

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:

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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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