IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Pharmacovigilance QMS & Inspection Preparation

26-27 April 27
+ 7-8 October 27

This course is designed to help participants understand pharmacovigilance quality management systems (QMS) and the principles and practical application of risk-based audits to ensure Regulatory compliance.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

Since the introduction of new pharmacovigilance legislation in the EU in 2012 and continuing updates, Quality Management Systems (QMS) and self-audits have become increasingly critical to satisfy Regulatory expectations. Regulators now expect companies to justify and implement risk-based audits and to clearly demonstrate continual improvement of processes, systems, and regulatory compliance. This responsibility extends across the entire organisation - from senior leadership through to clinical, pharmacovigilance, sales and marketing, IT, and medical services teams.

This must-attend course clearly explains the principles, practical approaches, and regulatory expectations for pharmacovigilance QMS and risk-based audits. It has been carefully designed to support both effective risk assessment and the full Corrective and Preventive Action (CAPA) process.

The highly interactive programme combines expert-led presentations, real-life case studies, and practical workshop sessions. This dynamic format ensures participants not only understand the concepts, but also gain hands-on experience and actionable skills they can immediately apply in their roles.

Benefits of attending

- **Explore** pharmacovigilance quality management systems (QMS) and risk-based audits, gaining practical insight into regulatory expectations and best-practice approaches
- **Learn** the importance of key performance indicators (KPIs) within your QMS, and how they support performance monitoring, compliance, and continuous improvement
- **Ensure** compliance through robust assessments of risk and effective implementation of your CAPA plans
- **Discuss** pharmacovigilance inspections and QMS activities, supported by real-world examples and interactive group discussion

Who should attend

This course is designed for QA representatives responsible for PV auditing, EU QPPVs, and professionals working in pharmacovigilance, regulatory, clinical, and administrative roles who are responsible for the management of CAPA systems, including:

- Pharmacovigilance professionals
- QA PV Auditors
- Regulatory professionals
- Clinical professionals
- Administrators responsible for CAPA management
- PSMF Personnel

All attendees will benefit from practical insights, regulatory guidance, and tools to support compliance and continuous improvement.

Presenter



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

26-27 April 27	**Live online** 09:00-16:15 **UK (London)** (UTC+01) *Course code 17117*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 01 Mar**
7-8 October 27	**Live online** 09:00-16:15 **UK (London)** (UTC+01) *Course code 17400*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 12 Aug**

How to book

Online:
ipi.academy/2385

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

★★★★★

5-excellent. Practical advices, Real life experience, answers to questions.

Maria Seifert
Senior Global PV Specialist
Acino AG
Sep 25 2025

★★★★☆

It was really good for basic knowledge and understanding of PV audit/inspection preparation. The many examples was great.

Susie Christensen
QPPV and regulatory Affairs specialist
2care4 Generics ApS
Sep 25 2025

★★★★☆

The material was spot-on for bridging the gap between routine PV operations and advanced regulatory preparedness. As someone knee-deep in ICSR processing, I particularly appreciated the deep dives into QMS frameworks Clear, logical flow with well-paced slides that avoided overload—great for a full-timetable day. Speaker was an absolute expert: confident, relatable, and generous with anecdotes from industry inspections that made the content feel immediate and applicable. Highly recommended for PV professionals looking to strengthen compliance foundations, with minor room for more interactive elements.

Justin Goh
Senior Safety Data Professional
Lundbeck Singapore Pte. Ltd.
Sep 25 2025

★★★★☆

The webinar is very good. [I particularly liked] real life examples from audits faced and conducted.

Bharati Perumalla
PV QA Manager
ALPHAMED FORMULATIONS PRIVATE LIMITED
Jan 20 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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