IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Pharmacovigilance QMS & Inspection Preparation

25-26 September 2025

This course is designed to help understand pharmacovigilance quality management systems (QMS) and risk-based audits.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

Since the introduction of the new pharmacovigilance legislation in the EU, QMS and self-audits have become an increasingly important topic. Companies have been challenged by regulators to implement risk-based audits where continual improvement of processes, systems and compliance to regulations needs to be demonstrated. This is required from the top of the company organisation in all areas of regulatory activity including clinical, pharmacovigilance, sales and marketing, IT and medical services.

This must-attend course will explain principles, approaches and regulatory expectations for the pharmacovigilance QMS and risk-based audits and has been designed to help in both the assessments of risk and the whole CAPA process. The highly participative programme will include a mix of presentations from our expert trainer, reallife case studies and practical workshop sessions which will help consolidate learning.

Benefits of attending

- **Explore** pharmacovigilance quality management systems (QMS) and risk-based audits
- **Learn** the importance of key performance indicators (KPIs) in your QMS
- **Ensure** compliance with assessments of risk and your CAPA plans
- **Discuss** pharmacovigilance inspections and QMS activities

Who should attend?

QA representatives, EU QPPVs and all working in pharmacovigilance, regulatory, clinical and administrators responsible for the management of the CAPA systems will benefit from this course.

Programme

Day 1

The audit basics

- The purpose of an audit
- Qualifications of the auditor
- The audit SOP and design
- The difference between audits and inspections
- Audit planning and risk assessments

The legislation and audits

- The requirements to perform company audits
- In-house versus external audits
- What needs to be audited
- Which departments need auditing for safety?

QMS

- QMS design
- Quality cycles – expectations and deviations
- Quality risk assessments
- KPIs
- Quality failings and corrections

QMS and the audit report

- The audit scope and conduct
- The audit report content
- The grading of audit reports
- Corrective action plans (root cause analysis)
- Re-audits

Workshop session

You will be asked to design the QMS for a safety department that has recently been audited. You will need to devise a plan based on any risk elements and audit findings identified and look at designing a QMS approach with KPIs.

Day 2

Introduction to PV inspections

- Background
- Purpose – design
- Roles and responsibilities of the licence holder
- Conduct of regulatory inspections

Risk-based inspections

- Defining risk
- Routine and for-cause inspections
- Triggers for an inspection
- Who should attend the inspection?

The pharmacovigilance inspection cycle

- Pre-inspection questionnaires
- Site visits and telephone audits
- Results and CAPAs
- Inspection follow-up questionnaires
- Follow-up inspections

Workshop session

You will be presented with a series of findings from a regulatory inspection. You will have to look at the findings and work out priorities, devise root cause analyses and provide detailed CAPA plans which will include QMS activities.

Common findings from regulatory inspections

- Grades of findings (and how to grade findings)
- How to grade findings in the same PV area
- Allied findings in other departments
- KPIs versus legislation
- Variations in major authority inspections

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

25-26 September 2025 **Live online**
09:00-16:15 **UK (London)** (UTC+01)
Course code 14950

GBP **1,299** ~~1,499~~
EUR **1,819** ~~2,099~~
USD **2,087** ~~2,399~~
Until 21 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

★★★★☆

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

★★★★★

Excellent, his experience and extensive knowledge are evident. It's been a pleasure to learn from him. I really liked the presentation and the speaker. Clear ideas, all the topics covered, and practical exercises to put the theory into practice.

Eva Sanz Castel
GSM QA AUDITOR
Lab Esteve
Sep 28 2023

★★★★★

[The presenter] has huge knowledge and gave real-life examples... the best thing was the practical exercise it will be a great guide to us.

Hind T. Almanea
QPPV
PharmaKnowl
Jan 23 2023

★★★★★

Graeme is very skilled professional, who was able to transfer example from real life experience and deliverables in a straightforward and effective way.

Mario Caiano
Pharmacovigilance Auditor
Pharmanovia
Jan 23 2023

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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