IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Clinical Quality Management Systems

18-19 September 2025

A two-day course that will ensure you comply with new regulatory requirements.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

With increasing clinical quality standards required by inspectors, there is currently no harmonised regulatory guidance for clinical quality management systems (CQMS), although there are multiple documents from different sources across the pharmaceutical and medical device industries. The regulators however, both in Europe and the US, expect an effective QMS to be in place for clinical development. Organisations are struggling to effectively implement and integrate these QMS standards, including ISO 9000 principles, ICH10 for CQMS and ICH GCP R2 and R3 CQMS requirements.

This course will provide essential information and guidance to help you achieve regulatory compliance in this evolving area of clinical quality, including EMA guidance on computerised systems and ICH GCP R3 data governance.

Who should attend?

This course is aimed at anyone working in clinical research or associated functions, including regulatory affairs and document management, who needs to know how to establish, maintain, monitor and improve a CQMS that focuses on product quality and compliance to GCP.

The programme will also be of value to those working in quality assurance and quality improvement roles in clinical research, management responsible for governance of CQMS and anyone working with or in clinical research who needs to comply with the new requirements for CQMS, including study sites.

It is ideal for those implementing a CQMS, those wanting to share best practice and anyone wanting an update on new developments in this area.

Benefits of attending

- **Understand** developing regulatory requirements for clinical quality management systems (CQMS)
- **Review** proposed CQMS framework
- **Consider** best practice in key CQMS areas

Programme

Day 1

What is clinical quality and CQMS?

- Quality principles and definitions
- Proposed CQMS framework

New industry CQMS framework

- The components of a CQMS
- Quality by design – what does it mean and how does it apply to clinical research and the CQMS?

QMS – compliance deficiencies

- What are inspectors looking for?
- Feedback from the regulators – hot inspection topics and trends
- Balancing strict regulations and progress in research

Documentation supporting CQMS

Enrol or reserve

Day 2

Importance of KPIs in your QMS and governance

- Documentation of KPIs and key performance tolerance levels
- Quality tolerance limits (QTL)
- Management review and governance of a CQMS

Risk-based component of CQMS

- Risk methodologies to include in CQMS
- ICH GCP R2 and R3 risk-based elements of a CQMS

Vendor oversight

- Outsourcing and partnership
- Demonstrating and documenting vendor oversight to inspectors
- Metrics and KPIs

Issues and CAPA management

- Correction, corrective action, preventive action and root cause analysis

Key consideration for computer systems and governance and validation

- Essentials of validation
- EMA guidance on computer systems
- ICH GCP R3 governance
- What are inspectors looking for?
- AI

QMS – technology solutions

- Examples of technology solutions and support technologies for CQMS

Presenter

Laura Brown

Dr Laura Brown is an independent pharmaceutical QA, management and training consultant and senior lecturer for the MSc in Clinical Research at the School of Pharmacy, University of Cardiff. Laura has more than 20 years' experience of quality assurance and managing international clinical trials. She has worked for several companies including GSK, Hoechst Marion Roussel, Good Clinical Research Practices and Phoenix International and has consulted with numerous pharmaceutical companies and suppliers to the pharmaceutical industry as well as academic institutions concerning quality management. Laura has an MBA with specialisation in project management, including quality assurance.

Course date

18-19 September 2025 **Live online**
09:30-17:00 **UK (London)** (UTC+01)
Course code 14930

GBP **1,299** ~~1,499~~
EUR **1,819** ~~2,099~~
USD **2,087** ~~2,399~~
Until 14 Aug

How to book

Online:
ipi.academy/2421

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

★★★★★

Very knowledgeable and presented information in a concise, easy to understand way

Joanna Faraj
Quality System Manager
Mitsubishi Tanabe Pharma Europe
Jan 25 2024

★★★★★

Very knowledgeable and presented information in a concise, easy to understand way

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★★★★☆

I really enjoyed the course. Content was very interesting, presentation material well done and it was possible to ask lots of questions. Laura is a very experienced speaker and she knows how to get the audience's attention.

Yvonne Wiggenhauser
Process Document Manager
Takeda Pharmaceuticals International AG
Nov 14 2019

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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