IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Clinical Quality Management Systems (CQMS): A Practical Guide to Inspection Readiness

15-16 March 27
+ 16-17 September 27

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

Regulators in both Europe and the US expect organisations involved in clinical development to have an effective Clinical Quality Management System (CQMS) in place, even though there is no single, harmonised regulation that defines exactly what that system should look like.

As a result, many organisations struggle to interpret and apply overlapping requirements from sources such as ICH Q10, ICH GCP (R2 and R3), ISO quality principles, and regulatory guidance on data governance and computerised systems. CQMS arrangements are often fragmented, inconsistently applied, or poorly documented, leaving teams exposed during inspections.

This course focuses on what regulators actually expect to see in practice, and how to implement and maintain a proportionate, inspection-ready CQMS that works in real clinical development environments. The emphasis is on practical application rather than theory.

Benefits of attending

- **Understand** current regulatory expectations for CQMS in clinical research and how they are applied in inspections
- **Recognise** the key components of an effective CQMS and how they link together across the clinical lifecycle
- **Identify** common CQMS weaknesses highlighted during regulatory inspections and how to avoid them
- **Apply** risk-based thinking to CQMS design, oversight and documentation
- **Understand** how data governance, computerised systems and vendor oversight fit within a CQMS
- **Feel** more confident explaining and defending your CQMS to inspectors

Who should attend

This course is designed for professionals involved in clinical research who have responsibility for, or interface with, clinical quality systems, including:

- Clinical research and clinical operations professionals
- Quality assurance and quality management staff
- Regulatory affairs and document management personnel
- Study, programme and project managers
- Those responsible for governance, oversight or inspection readiness
- Service providers and study sites working within sponsor CQMS frameworks

The course is particularly useful for organisations implementing or refining a CQMS, teams preparing for regulatory inspections, and those seeking a practical update on ICH GCP R3-related CQMS expectations.

Programme

Day 1

Overview of CQMS landscape

What is clinical quality and CQMS?

- Quality Principles and Definitions
- Core quality concepts
- Relationship to ICH-GCP
- Risk-based quality management

Proposed CQMS framework

- New Industry CQMS Framework
- Governance structures
- Lifecycle approach
- Integration with risk management
- Recent industry developments

The Components of a CQMS

- Quality policy and objectives
- SOP hierarchy
- Training and competency
- Audit & CAPA systems
- Metrics and oversight

Quality by design (QbD)

- Definition and regulatory origin
- Application in clinical research
- Embedding QbD into CQMS

Day 2

QMS - compliance deficiencies

- What are inspectors looking for?
- Common inspection findings
- Systemic vs isolated issues
- Data integrity focus
- Oversight expectations

Feedback from regulators

- Hot inspection topics and trends
- Recent regulatory themes
- Risk-based monitoring focus
- Emerging global trends

Balancing strict regulations and progress in research

- Innovation vs compliance
- Digitalisation and AI
- Proportionality in quality systems

Documentation supporting CQMS

- Quality Manual
- SOP structure
- Quality plans
- Audit documentation
- Inspection readiness

Presenter



Laura Brown

Dr Laura Brown is an independent pharmaceutical quality assurance, management and training consultant and former Course Director of the MSc in Clinical Research at Cardiff University. She has over 25 years' experience working in quality assurance and the management of international clinical trials, across both industry and academia. Laura has worked in senior QA roles and with a range of organisations including GSK, Hoechst Marion Roussel, Good Clinical Research Practices, and Phoenix International.

Much of Laura's work has focused on helping companies and clinical teams make quality systems work in practice - not just on paper. She has supported pharmaceutical companies, CROs, suppliers, and academic institutions with the development and improvement of quality management systems, inspection readiness, and day-to-day compliance.

Laura holds an MBA with a specialisation in project management, and her teaching and training style is practical and experience-led, drawing on real examples from clinical research rather than theory alone.

Course dates

15-16 March 27	**Live online** 09:30-17:00 **UK (London)** (UTC+00) *Course code 17069*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 18 Jan**
16-17 September 27	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 17330*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 22 Jul**

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 **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

★★★★☆

good presenter.

Hanne Storgaard
Clinical Quality Operations Lead- Suppliers
MSD Denmark
Sep 18 2025

★★★★☆

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

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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:



ALEKSANDRA BEER
Tel: +44 (0)20 7749 4749
Email:
inhouse@ipiacademy.com



YESIM NURKO
Tel: +44 (0)20 7749 4749
Email:
inhouse@ipiacademy.com



Harry ALTAMONT
Tel: +44 (0)20 7749 4749
Email:
inhouse@ipiacademy.com

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.

10-12 Rivington Street
London EC2A 3DU

ipi.academy
Tel: +44 (0)20 7749 4749
Email: info@ipiacademy.com