IPI Academy

MANAGEMENT forum

Presented by
Management Forum

ICH GCP E6(R3) Implementation: What You Must Be Doing Now

13 July 2026

Get clear, actionable guidance on E6(R3) requirements for digital tools, AI, risk-based approaches, and quality-by-design. Learn how to apply them to trial conduct, oversight, and regulatory readiness using real-world examples.

Format:
Live online

CPD:
6 hours for your records

Certificate of completion

Course overview

The long-awaited ICH GCP E6(R3) guideline has now been released, and with implementation from July 2025, clinical research teams must move from awareness to action. This one-day course provides a clear, practical understanding of the new requirements and how they affect day-to-day clinical research activities.

The course covers all core elements of ICH GCP E6(R3), including the updated expectations for digital technologies, automated systems and algorithmic/AI-enabled tools used in clinical trials. Participants will gain practical clarity on how R3 applies to modern data systems, proportional risk-based approaches, documentation, and oversight obligations. Regulators will increasingly expect organisations to demonstrate alignment with the updated principles - meaning preparation is essential.

E6(R3) represents the most significant shift in GCP in more than a decade, bringing stronger emphasis on Critical-to-Quality (CtQ) factors, quality-by-design thinking, enhanced data integrity requirements, and clearer shared responsibilities across sponsors, investigators, and service providers.

Rather than focusing on theory alone, this course uses real-world examples and practical scenarios to show how R3 should influence trial design, conduct, monitoring, vendor management, and inspection readiness. Whether your organisation has already begun transitioning or is just starting to implement, this course provides the insight, structure, and direction needed for smooth and compliant implementation.

Benefits of attending

- **Understand** the key changes in ICH GCP E6 (R3) and why they matter now that implementation is underway
- **Learn** what regulators will expect to see as evidence of transition and readiness
- **Gain** clarity on risk-based, proportional approaches and how to integrate them into daily trial practices
- **Strengthen** your understanding of revised sponsor, investigator, and service provider responsibilities
- **Improve** documentation and data governance processes to align with the new standard
- **Reduce** the likelihood of inspection findings by ensuring your processes reflect E6(R3)

Who should attend

This course is ideal for clinical research professionals who need to understand and apply the new E6(R3) requirements in their daily work, including:

- Clinical Research Associates (CRAs) and Clinical Research Coordinators (CRCs)
- Clinical Trial Managers (CTMs) and Project Managers
- Quality Assurance professionals
- Regulatory Affairs and compliance specialists
- Investigators and study site staff
- Sponsors, CRO teams, and service providers involved in trial oversight
- Anyone responsible for ensuring alignment with ICH GCP E6 (R3)

Presenter

Laura Brown

Dr Laura Brown is an independent quality assurance and training consultant with extensive experience in clinical research and GCP compliance. She was formerly Course Director of the MSc in Clinical Research at the School of Pharmacy, Cardiff University, and Course Director of the MSc in Regulatory Affairs at the University of Hertfordshire.

Laura has managed and supported GCP inspections across the pharmaceutical industry and has held roles including Clinical Research Manager, Audit Director and Head of Training. She chaired the Institute of Clinical Research GCP Forum for six years and writes regularly on clinical research regulatory requirements, including ICH GCP E6 (R2) and (R3).

Course date

13 July 2026	**Live online** *Course code 16055*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 08 Jun**

How to book

Online:
ipi.academy/3261

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

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