IPI Academy

MANAGEMENT forum

Presented by
Management Forum

ICH GCP E6 (R3): What You Need to Know for Implementation and Inspection

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

This course focuses on the practical implications of the ICH GCP E6 (R3) guideline and what it means for the conduct and oversight of modern clinical trials. While the core principles of GCP remain unchanged, E6 (R3) introduces clearer expectations around risk-based approaches, oversight, roles and responsibilities, and the use of data and technology.

The course is designed to help clinical research professionals understand what has changed, how organisations are applying the new requirements in practice, and what regulators and inspectors are likely to focus on during GCP inspections.

Through practical examples, the session explores how sponsors, CROs and investigator sites are adapting governance, oversight, and decision-making under E6 (R3), with particular focus on inspection readiness.

By the end of the course, delegates will have a clear understanding of how to implement ICH GCP E6 (R3) in a practical and inspection-ready way.

Benefits of attending

- **Understand** the key updates and principles of ICH GCP E6 (R3)
- **Learn** how the E6 (R3) requirements are being implemented by companies, using practical examples
- **Understand** how GCP inspections are evolving under E6 (R3) and what inspectors are likely to focus on
- **Apply** risk-based approaches to clinical trial design, oversight, and monitoring
- **Share** experiences and insights with peers facing similar implementation challenges

Who should attend

This course is suitable for anyone involved in the planning, conduct, oversight, or support of clinical trials. It is applicable across Pharma, Biopharma, Clinical Research Organisations (CROs), service providers, and investigator sites.

While focused on ICH GCP E6(R3), the principles discussed are relevant to any organisation involved in the conduct and oversight of regulated clinical investigations.

The course is particularly relevant for:

- Clinical Research Associates (CRAs)
- Clinical Trial Managers and Project Managers
- Regulatory Affairs Professionals
- Quality Assurance Personnel
- Investigators and Site Staff
- Data Managers
- Anyone involved in the design, execution, oversight, or governance of clinical trials

Programme

Introduction and objectives

- Introduction to ICH GCP E6 (R3)
- Core Principles of ICH GCP E6 (R3)

Stakeholder responsibilities

- Roles of Institutional Review Boards (IRBs)/Independent Ethics Committees (IECs)
- Investigator obligations
- Sponsor Responsibilities
- Service providers

Risk-based approaches

Data governance and integrity

Data and records

Investigator brochures

Protocols

Essential records

Preparing for regulatory inspections

Implementation considerations

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
09:30-17:00 **UK (London)** (UTC+01)
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