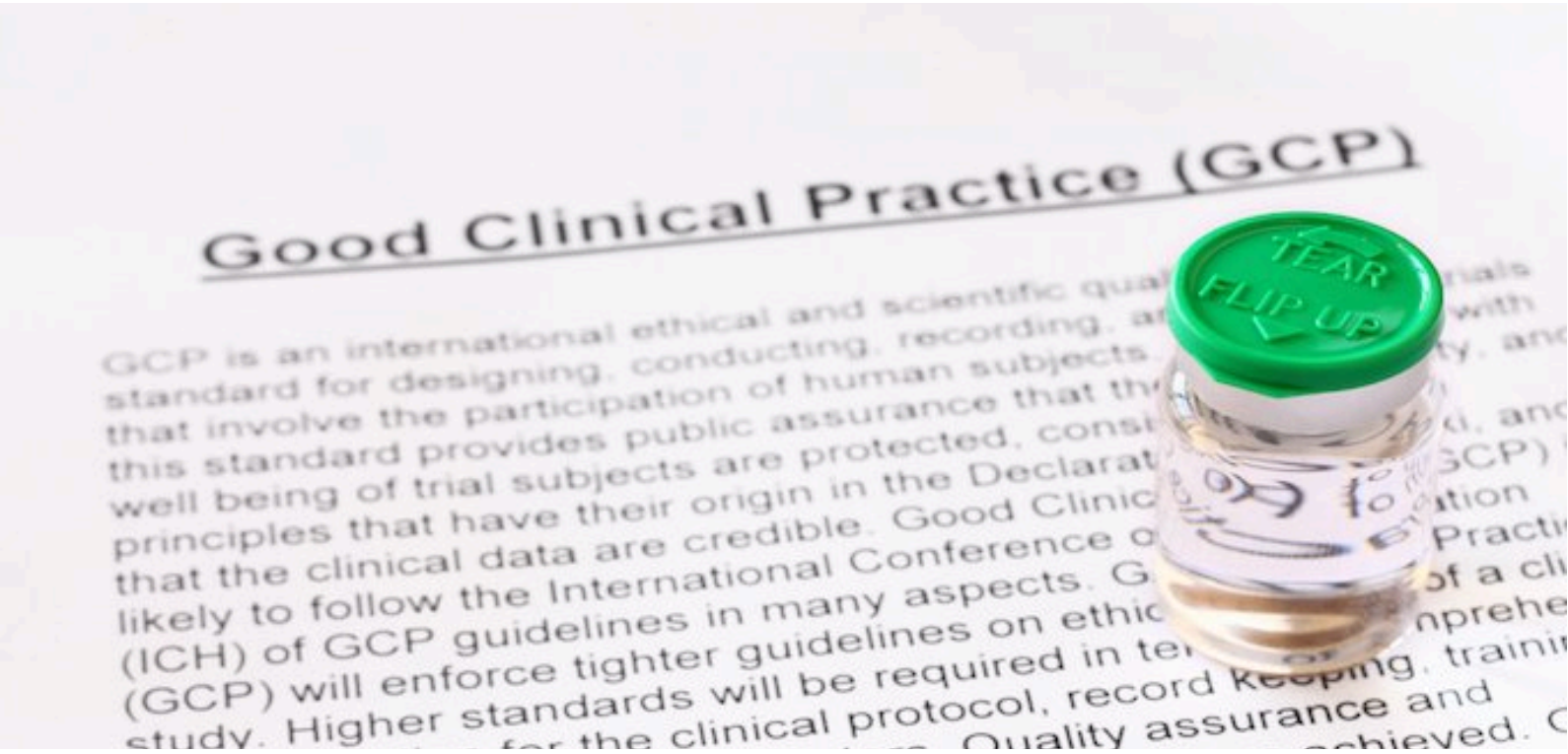
IPI Academy

MANAGEMENT forum




*Presented by*
**Management Forum**

# GCP and Clinical Research Update: What Inspectors Are Focusing on Now

**19 May 2026**
+ 20 November 2026

This course provides the latest updates on the finalised ICH GCP E6 R3 guideline, EU Clinical Trial Regulation update, other EU and FDA requirements, consideration for managing studies in the future and AI and other technology developments.

**Format:**
Live online

**CPD:**
6 hours for your records

Certificate of completion

# Course overview

**Clinical research regulation continues to evolve, and keeping up with changes in GCP is an ongoing challenge for anyone working on clinical trials. Inspectors expect trial teams to understand not only what has changed in guidance and regulation, but how those requirements are being interpreted and applied in practice.**

This one-day course provides a focused and practical update on the areas of GCP and clinical research regulation that are currently attracting the most attention during EU and FDA inspections. Rather than attempting to review regulatory guidance on a document-by-document basis, the course concentrates on how key principles from ICH GCP E6(R3), the EU Clinical Trials Regulation, and selected EU and FDA guidance are being tested during inspections.

The programme brings together:

- Recent inspection trends and common findings
- Practical interpretation of ICH GCP E6(R3) and related guidance
- EU Clinical Trials Regulation requirements and CTIS expectations
- FDA and EU regulatory thinking as reflected in inspection focus areas, questions, and observations

Throughout the day, EU and FDA guidance is addressed through inspection outcomes, regulatory expectations, and real-world examples, helping participants understand what inspectors are looking for now and how to demonstrate compliance in practice. The emphasis is on interpretation, prioritisation, and practical impact on trial conduct, rather than theoretical review of guidance documents. The course is designed to help delegates refresh their knowledge, feel confident discussing current regulatory expectations during audits and inspections, and apply up-to-date GCP principles to how trials are actually run.

## Benefits of attending

By attending this course, participants will:

- **Gain** a clear overview of current inspection focus areas
- **Understand** the most important changes introduced by ICH GCP E6(R3)
- **Clarify** expectations around risk-based approaches, governance, and oversight
- **Refresh** their understanding of essential documentation and TMF requirements
- **Understand** how data integrity is being assessed by inspectors
- **Explore** how inspectors are viewing technology, digitalisation, and AI in trials

## Who should attend

This course is suitable for professionals who need to stay current with GCP requirements and inspection expectations, including:

- Clinical Research and Clinical Operations professionals
- Regulatory Affairs professionals supporting clinical trials
- Quality Assurance and Audit professionals
- Pharmacovigilance professionals involved in trial oversight
- CRO and vendor staff working with sponsors
- Academic trialists involved in regulated studies

It is particularly relevant for those who need to demonstrate recent and up-to-date GCP training during inspections.

# Programme

**Inspection trends and common findings**

- Overview of recent EMA, MHRA, and FDA inspection themes
- Areas where organisations are most frequently challenged

**ICH GCP E6(R3): what has changed**

- Key updates and revised expectations
- Annex 1: what it means in practice
- Risk-proportionate approaches and governance
- Links to ICH E8 and quality by design

**Data integrity and trial oversight**

- What inspectors expect to see
- Common weaknesses and how they arise
- Practical steps to strengthen data integrity governance

**EU Clinical Trials Regulation (536/2014)**

- Key requirements and practical implications
- CTIS: common challenges and inspection considerations
- Serious breaches and reporting expectations

**Essential documents and the TMF**

- Common TMF-related findings
- Structure, control, and oversight of the TMF
- eTMF considerations, archiving, and retention

**Technology and future considerations**

- Digitalisation and decentralised trials
- Electronic informed consent
- Real-world data in clinical research
- Artificial intelligence: current regulatory thinking

# Presenter

**Laura Brown**

Dr Laura Brown is an independent QA and training consultant and director of the MSc in Clinical Research, School of Pharmacy, University of Cardiff. Laura has many years' experience of managing GCP inspections in the pharmaceutical industry and has worked for several leading companies including GSK, Hoechst Marion Roussel, Good Clinical Research Practices and Phoenix International. She has worked as a clinical research manager, audit director and head of a training department. She is an international expert on GCP and clinical trial requirements and was chair of the Institute of Clinical Research GCP Forum for six years. Laura writes regularly on clinical research regulatory requirements and has written a chapter in International Pharmaceutical Product Registration and several articles on the EU Clinical Trial Regulation, Brexit, and ICH GCP R2.

# Course dates

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|---|---|---|
| **19 May 2026** | **Live online**<br>09:30-17:00 **UK (London)** (UTC+01)<br>*Course code 16181* | GBP **649** ~~749~~<br>EUR **909** ~~1,049~~<br>USD **1,043** ~~1,199~~<br>**Until 14 Apr** |
| **20 November 2026** | **Live online**<br>09:30-17:00 **UK (London)** (UTC+00)<br>*Course code 16558* | GBP **649** ~~749~~<br>EUR **909** ~~1,049~~<br>USD **1,043** ~~1,199~~<br>**Until 16 Oct** |

## How to book

**Online:**
ipi.academy/2384

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 overview was great, information clear and shared with links.**

**Ana Karla Uribe Rivera**
Research Fellow of Image Guided Surgery
IHU, Strasbourg
Jul 1 2024

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★★★★★

**Very well done and would recommend to others**

**Jaclyn Verrow**
Director, TMF Compliance & Oversight
Vertex Pharmaceuticals
Mar 10 2023

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★★★★★

**Very good presentation and useful information with links, examples and clips which made it more interesting.**

**Kianoosh Khaksar**
Compliance Specialist
Lundbeck
Mar 10 2022

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★★★★★

**[Laura] is a good presenter, she has world of knowledge. She was also able to get open discussion with the participant which made the course more interesting.**

**Angelo Jacala**
Director, Clinical QA
MEI Pharma
Sep 24 2021

## 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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