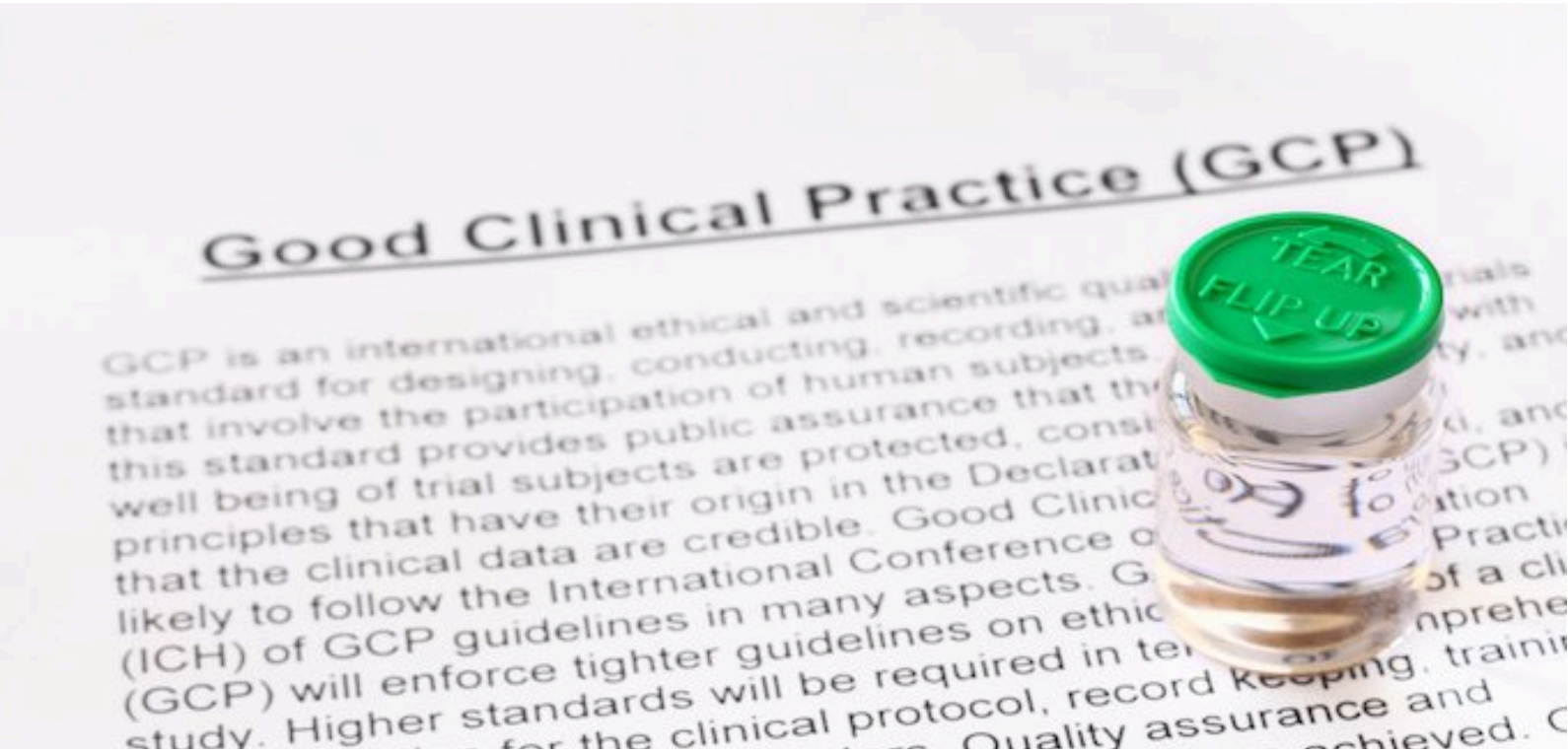
IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Preparing for GCP Inspections: Key Expectations under ICH GCP E6(R3), EU CTR and Current Regulatory Thinking

25 May 27
+ 19 November 27

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

Regulatory expectations in clinical research continue to evolve, particularly with the introduction of ICH GCP E6(R3) and the implementation of the EU Clinical Trials Regulation (CTR). Regulators are increasingly focusing on risk-based governance, data integrity, oversight of vendors and CROs, and the use of technology and digital processes in trials.

This practical one-day course focuses on what inspectors from EU authorities, the MHRA and the FDA are currently looking for during inspections. Rather than reviewing guidance documents in isolation, the programme concentrates on how regulatory expectations are interpreted and applied in real inspection situations.

Participants will gain a clear understanding of the most common inspection findings, how organisations are challenged by regulators, and the practical steps that clinical teams can take to demonstrate compliance and inspection readiness.

Benefits of attending

- **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 assessed during inspections
- **Explore** how inspectors view 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 up-to-date GCP training during inspections or audits.

Programme

Inspection trends and common findings

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

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

25 May 27	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 17197*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 30 Mar**
19 November 27	**Live online** 09:30-17:00 **UK (London)** (UTC+00) *Course code 17504*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 24 Sep**

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

★★★★★

Very well done and would recommend to others

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

★★★★★

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

Kianoosh Khaksar
Compliance Specialist
Lundbeck
Mar 10 2022

★★★★★

[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.

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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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