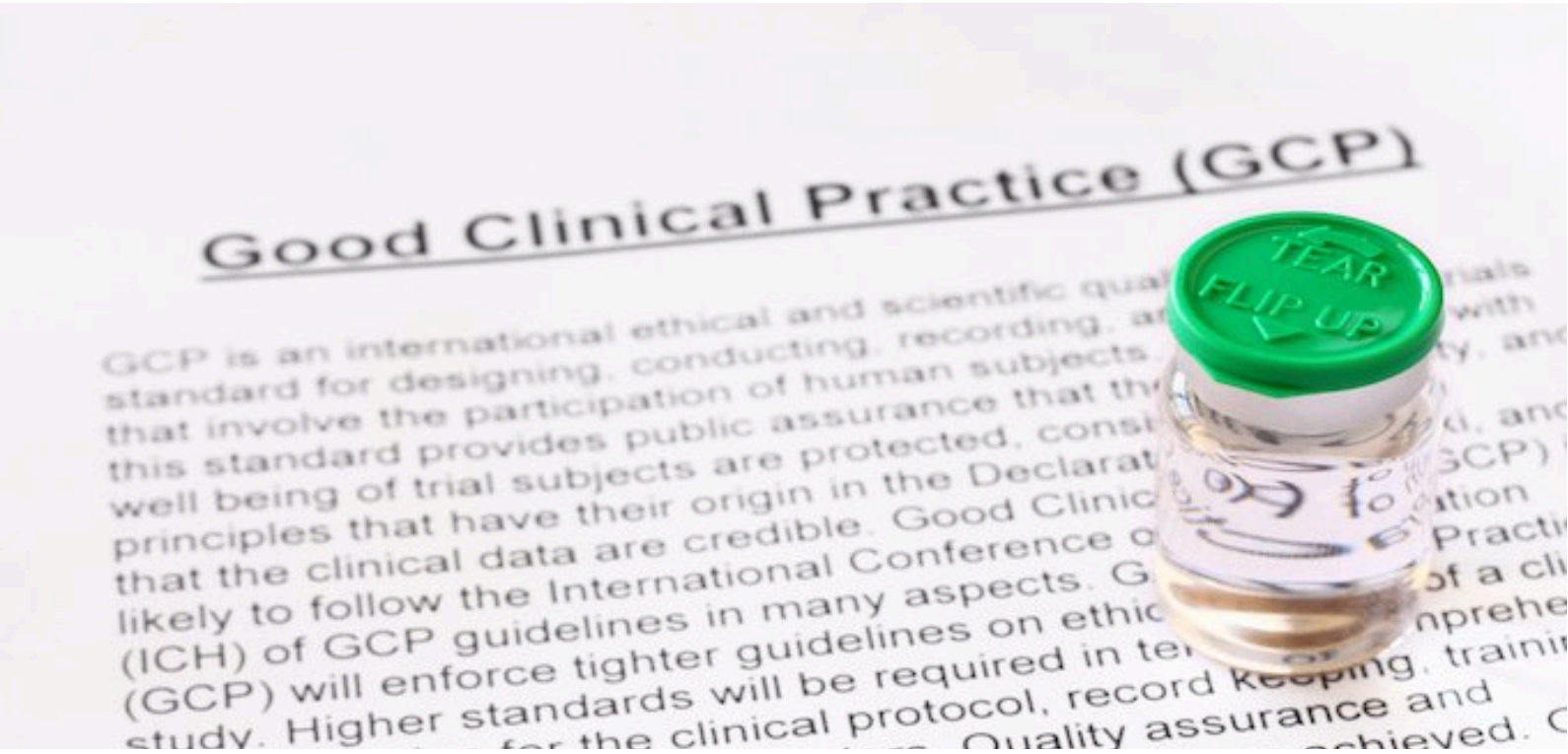
IPI Academy

MANAGEMENT forum



Presented by
Management Forum

GCP and Clinical Research Update - Hot Inspection Topics

7 July 2025
+ 21 November 2025

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 is a constantly evolving field and the regulatory requirements are frequently being updated. In order to stay ahead and maintain your GCP knowledge, it is important to receive regular training.

This must-attend course provides a review of recent changes to relevant guidance and legislation and will look at how these developments have been implemented and are likely to be implemented. Topics covered will include the EU Clinical Trials Regulation and associated documents and an update on ICH GCP R3

This is a highly interactive course suitable for those who need to refresh their knowledge and to demonstrate recent and up-to-date training to regulatory inspectors.

Benefits of attending

- **Be updated** on ICH GCP R3
- **Discuss** recent developments in GCP and clinical trial legislation and guidance in the EU, FDA considerations
- **Review** the requirements of clinical trail essential documentation
- **Identify** common audit and inspection findings to help prepare for inspection
- **Understand** the EU Clinical Trial Regulation requirements
- **Clarify** requirements for data integrity and governance
- **Explore** technology advances in clinical trials

Who should attend

The course is of particular relevance for those working in clinical research, regulatory affairs and pharmacovigilance, QA, Audit, CROs, academic trialists and regulatory inspectors. It will also be of interest to those departments who liaise/support clinical trial personnel and all other professionals who want to know more about updates in GCP regulations and guidelines covering clinical trials.

Programme

Brief review of regulatory authority inspections findings

EMA, MHRA and FDA findings

Latest ICH GCP E6 R3 guideline

- Develop an understanding of the ICH GCP E6 R3, focusing on the critical updates and revisions
- The key new requirements introduced by the latest E6 R3 Annex 1 guideline
- Risk-proportionate approaches
- What will impact on running clinical trials
- ICH E8 implications for ICH GCP E6 R3

Data integrity governance

- What inspectors look for
- MHRA integrity guidance compliance
- ICH GCP E6 R3 Governance requirements

EU Clinical Trial Regulation (536/2014) update

- Key requirements and documentation
- Clinical Trials Information System (CTIS)
- EU clinical trial authorisation
- Serious Breaches

Essential records: EMA key requirements to avoid inspection findings, and documents requirement in ICH GCP E6 R3

- TMF structure, content, security, control, maintaining the TMF and storage, e-TMFs, archiving and retention
- ICH GCP E6 R3 - recommended format for compliance

Awareness update from EU and FDA

- **EU**
  - EMA Guidance on validation & qualification of computerised systems
  - European Commission Guidelines on Good Clinical Practice specific to Advanced Therapy Medicinal Products (ATMPs)
  - Artificial intelligence reflection guidance in lifecycle
  - Stronger enforcement of the GDPR in cross-border cases
  - Real-world data
- **FDA**
  - Guidance for industry: considerations for the use of real-world data
  - FDA guidance on enhancing the diversity of clinical trials
  - A risk-based approach to monitoring of clinical investigations
  - Informed consent guidance for IRBs, clinical investigators and sponsors

Digitalisation and technology advances and GCP

- Technology innovations in clinical research
- Electronic informed consent
- Apps, medical devices and mobile technologies in clinical trials
- Artificial intelligence
- Decentralised clinical trials

Conclusion and final Q&A

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

7 July 2025	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 14788*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 02 Jun**
21 November 2025	**Live online** 09:30-17:00 **UK (London)** (UTC+00) *Course code 15087*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 17 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 **15% 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.

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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