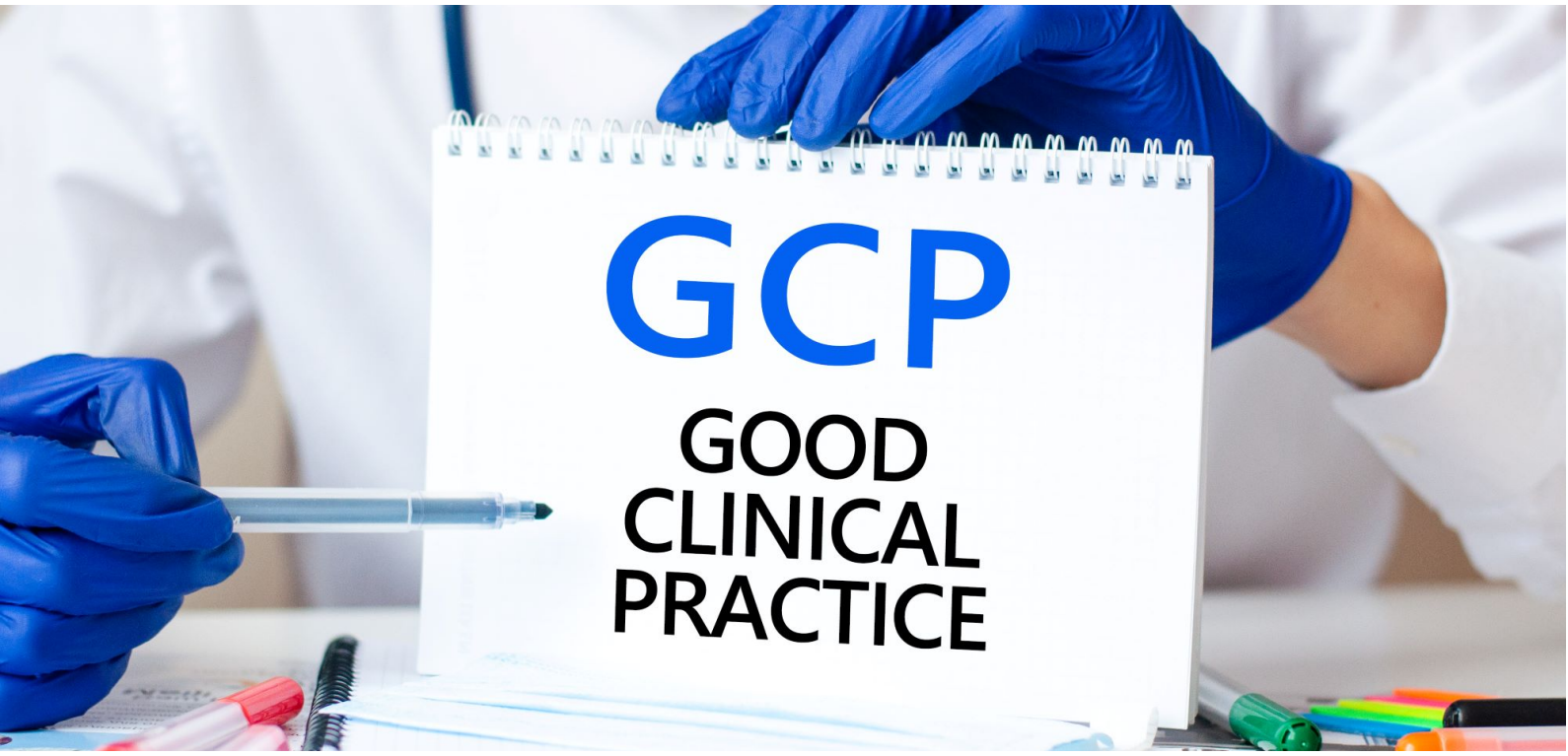
IPI Academy



Presented by
Management Forum

Introduction to Good Clinical Practice (GCP)

11-12 February 2025
+ 24-25 June 2025, 7-8 October 2025

This course will introduce you both to the principles of GCP, and give you an understanding of how this applies in different settings.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, recording and reporting trials that involve the participation of human subjects. GCP exists to both protect participants and ensure the integrity of data.

GCP training is an essential requirement for all researchers conducting Clinical Trials of Investigational Medicinal Product (CTIMPs) and is recommended learning for researchers involved in observational trials. There are different responsibilities of GCP depending on if you are the study sponsor, the Contract Research Organisation delegated to manage the study, or are working at the site.

This two-day introductory course gives attendees the opportunity to learn the basics of GCP, as well as understand how to apply GCP throughout the research lifecycle.

Benefits of attending

- **Understand** the importance of Good Clinical Practice in clinical research studies
- **Learn** about how to apply Good Clinical Practice to real world settings
- **Gain** an opportunity to discuss Good Clinical Practice scenarios with experts with industry, academic and NHS experience

Who should attend?

- Sponsor personnel responsible for trial design, sponsorship or ethical applications
- CRO personnel involved in regulatory processes, site set up, monitoring or close out activities
- Site personnel involved in regulatory processes, site set up, monitoring or close out activities

Programme

Day 1

Introduction to GCP, including the historical context

- Interactive opportunities to gauge current knowledge and deliver didactic training slides

The role of institutional review boards in GCP

- Didactic training slides supported with a role play of an IRB around a key GCP issue

Informed consent and GCP

- Instructor led example of poor informed consent with breakout rooms to dissect what we can learn from bad practice
- Didactic training slides to support learning

Participant safety and wellbeing in the context of GCP, including: data safety, security and confidentiality

- Return from break quiz on hot safety topics in GCP
- Didactic training slides to review key areas
- Scenario discussions to apply learning to real world setting

Deviations, violations and serious breaches

- Didactic training slides
- Break out rooms to discuss scenarios to apply learning to different perspectives (sponsor, site, CRO)

Day 2

GCP and the protocol

- Breakout rooms assigned to sections of the protocol to discuss how GCP influences or is apparent in protocol design
- Didactic training slides
- Activity linking protocol design day 1 topics (IRB, Informed Consent, Safety), supported with didactic training slides

The importance of good documentation and the ALCOA principles

- Quiz on documentation supported by examples of common errors in documentation
- Didactic training slides to introduce principles and highlight key learnings

Who does what: roles and responsibilities in GCP

- Didactic slides to introduce key roles and responsibilities in a trial to align to GCP principles.
- Breakout rooms to create a roles and responsibilities matrix for a provided trial scenario.
- Didactic training slides to provide additional examples in different settings

Managing research misconduct

- Didactic training slides on topic
- Paired conversations on the soft skills needed for managing research misconduct (handling confrontation, difficult conversations)

Presenters

Joe Milne

Joseph is a clinical trials specialist who has worked in laboratory and contract research organisations, and has led a clinical trials team for one of the world's largest pharmaceutical companies. Joseph has a degree in Toxicology from Edinburgh Napier University and has been involved in research studies and clinical trials for over a decade. He is the Director of Clinical Research at Scottish Brain Sciences.

Sarah Gregory

Sarah is a postdoctoral researcher with a background in psychology, mental health and dementia clinical trials and large dementia prevention cohort studies. With experience of working in the NHS and academic institutions, she is particularly interested in Patient and Public Involvement work as well as ethical considerations of research, and is an active member of two research ethics committees. Sarah is the lead of a large cohort study at Scottish Brain Sciences and a research fellow at the University of Edinburgh.

Course dates

11-12 February 2025	**Live online** 09:00-16:30 **UK (London)** (UTC+00) *Course code 15341*	GBP **1,099** ~~1,299~~ EUR **1,589** ~~1,869~~ USD **1,817** ~~2,129~~ **Until 07 Jan**
24-25 June 2025	**Live online** 09:00-16:30 **UK (London)** (UTC+01) *Course code 15342*	GBP **1,099** ~~1,299~~ EUR **1,589** ~~1,869~~ USD **1,817** ~~2,129~~ **Until 20 May**
7-8 October 2025	**Live online** 09:00-16:30 **UK (London)** (UTC+01) *Course code 15343*	GBP **1,099** ~~1,299~~ EUR **1,589** ~~1,869~~ USD **1,817** ~~2,129~~ **Until 02 Sep**

How to book

Online:
ipi.academy/2817

Alternatively contact us to book, or if you have any queries:

Email:
info@ipi.academy

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

Run this programme in-house for your whole team

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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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