

Refresher Online Course

Course Overview

This interactive online GCP refresher training course is designed for individuals who have completed a full GCP course within the past two years. It refreshes core GCP principles while incorporating the latest ICH GCP E6 Revision 3 guidance, released in January 2025, reflecting current expectations for the conduct of clinical trials.

Participants will receive official GCP certification recognised by sponsors and CROs worldwide. The course supports ongoing compliance by reinforcing key responsibilities and highlighting recent updates to global GCP standards, helping learners stay current with evolving clinical trial requirements. The Faculty of Pharmaceutical Medicine has approved this online GCP training course for CPD points.

CPD Points Available: 4

Learning Objectives

- Understand the key principles, updates, and roles introduced in ICH GCP E6(R3) and their impact on clinical trials.
- Apply the updated GCP standards in your role to ensure compliance and improve trial conduct.
- Understand revised roles and responsibilities of investigators, sponsors, and key stakeholders under E6(R3).
- Apply updated risk-based approaches to assess and manage clinical trial risks, ensuring safety and compliance.
- Apply strategies to maintain data integrity, high-quality practices, and effective monitoring to strengthen oversight and compliance in clinical research.

Module One:

Chapter 1 - What is ICH GCP?

- What is Good Clinical Practice (GCP)?
- The Historical Context of GCP
- The International Council for Harmonisation
- ICH GCP Efficacy Guidelines (E6 R3)
- Terminology

Chapter 2 – Key Legislation and Regulations

- Key Legislation

Chapter 3 – Ethics and Safeguarding

- What Is an Ethics Committee and Why Do We Need It?
- Safeguarding

Chapter 4 – Clinical Trial Design

- Clinical Trial Design

Chapter 5 – Sponsor

- The sponsor

Chapter 6 – Investigator

- The investigator

Chapter 7 – Monitoring

- Monitoring
- Monitoring Visits and Reporting

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Module Two:

Chapter 8 – Participant Safety

- What is Participant Safety?
- Who is Responsible for Participant Safety?
- Safety Reporting

Chapter 9 – Informed Consent

- What is Informed Consent?
- How is Informed Consent Acquired?

Chapter 10 – Investigational Products

- What is IP?
- IP Responsibilities

Chapter 11 – Technology Including eTMF

- Technology

Chapter 12 – Data and Data Governance

- Recording Keeping and Data Handling
- Data Integrity (ALCOA++)
- Storing and Processing Data (GDPR)
- Data Governance

Chapter 13 – Quality

- Quality Management, QA and QC
- Risk Management
- Audits
- Noncompliance
- End of Trial, Participant Withdrawal or Trial Termination

Chapter 14 – E6(R3) Appendices

- Appendices – What Do These Include?
- Appendix A: Investigator’s Brochure
- Appendix B: The Clinical Trial Protocol and Amendments
- Appendix C: Essential Records for the Conduct of a Clinical Trial

Duration: Approx. 4 hours

As with all of our courses, you are able to take this in your own time, on any device and are able to pause and restart from the place you left off. Time taken will vary depending on your experience and how many of the many optional links and activities you choose to view.



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