ICH Good Clinical Practice (GCP) E6 R3

The Faculty of Pharmaceutical Medicine has approved this online GCP training course for CPD points.
CPD Points Available: 6

Introducing our newly updated, interactive, and engaging online training course, now aligned with the latest ICH Good Clinical Practice (GCP) E6 Revision 3 guidance which was released on 6th January 2025.
This course reflects the most recent changes in the GCP framework, designed to ensure compliance with current global standards for clinical trials.

Our course goes beyond merely rehashing the E6 R3 guidance. We have reimagined it, to include foundational knowledge and provide practical, actionable insights that can be directly applied to everyday situations in clinical research, empowering participants to navigate real-world challenges with confidence and expertise. Our comprehensive training is suitable for anyone involved in clinical research and will provide participants with official certification in GCP, recognised by sponsors worldwide.

Created by subject matter experts with over 35 years of experience in clinical research, this course incorporates the latest best practices and regulatory updates. It includes improved knowledge checks, video learning using AI technology and more interactive elements to make the learning experience even more engaging and effective.

This course meets the training requirements set forth by Transcelerate Biopharma Inc., and is ideal for investigator site personnel, ensuring you stay at the forefront of clinical research **standards.**

Stay ahead of the curve with GCP E6 R3 training that prepares you for the evolving landscape

Learning Objectives

- To understand the key changes in ICH GCP E6 R3
- To apply the core principles of GCP
- To navigate the new roles and responsibilities of clinical trial personnel
- To comprehend the regulatory framework for clinical trials
- To ensure effective risk-based management in clinical trials
- To promote data integrity and quality in clinical research
- To implement Improved monitoring and oversight practices
- To explain the new guidance on investigator and site management
- To identify how to effectively use technology to enhance compliance
- To prepare for the implementation of ICH GCP E6 R3 in your role

Duration: Approx. 6-8 hours

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Price: £159

Training Online 4U

COURSE CONTENTS:

MODULE ONE

Chapter 1: What is ICH GCP

- What is Good Clinical Practice (GCP)?
- What is a Clinical Trial?
- Key Roles in a Clinical
- Trial
- The Historical Context of GCP
- The International Council for Harmonisation
- ICH GCP Efficacy
- Guidelines (E6 R3)

Chapter 2 – Key Legislation and Regulations

- Regulatory and Advisory Bodies
- Key Legislation

Chapter 3 – Ethics and Safeguarding

- What is an Ethics
- Committee and why do we need it?
- Safeguarding

MODULE TWO

Chapter 4 - Clinical Trial Design

Chapter 5 – Sponsor

- The Sponsor
- Investigator and Monitor Selection

Chapter 6 – Investigator

- The Investigator
- Roles and Responsibilities

Chapter 7 – Monitoring

- What is Monitoring and why is it Necessary
- Monitoring Approaches
- Monitoring Visits and Reporting

MODULE THREE

Chapter 8 – Participant Safety

- The Participant
- 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 and Medical Devices

- What is IP?
- IP responsibilities
- What is a Medical Device?
- Data (GDPR)
- Data Governance

Chapter 11 – Technology Technology Including eTMF

Chapter 12 – Data Governance

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

Chapter 13 – Quality Quality Management, Risk, QA and QC

- Audits
- Risk Management
- End of Trial, Patient Withdrawal or Trial Termination
- Non-compliance

Chapter 14 - E6 R3 Appendices

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

- Summary
- Exam
- Accessing your certificate