Good Clinical Practice E6(R3) For Investigators Online Course

£159

Course Overview

The Faculty of Pharmaceutical Medicine has approved this online GCP training course for CPD points. CPD Points Available: 2.

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 aimed specifically at investigators. 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 investigators working 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 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 of clinical trials.

Learning Objectives

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

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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)
- ICH GCP efficacy guidelines (E6 R3)

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

Chapter 8 – Communication
- Communicating with RA and sponsor

Chapter 9 – Participant Safety
- What is Participant Safety?
- Who is Responsible for Participant Safety?
- Safety Reporting

Chapter 10 – Informed Consent
- What is Informed Consent?
- How is Informed Consent Acquired?

Chapter 11 – Investigational Products
- What is IP?
- IP responsibilities

Chapter 12 – Data
- Technology
- Trial Management, Data Handling and Recording Keeping
- Data Integrity (ALCOA++)
- Storing and Processing Data (GDPR)
- Data Governance

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

Chapter 14—Noncompliance and End of Trial
- Non-compliance
- End of Trial, Patient Withdrawal or Trial Termination

Chapter 15 - 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

Chapter 16—Exam
- Exam
- Accessing your Certificate

Duration: Approx. 2 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.