ICH Good Clinical Practice (GCP) E6 R3

Training Online 4U

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 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

Duration: Approx. 6-8 hours

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Price: £159

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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)
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 an investigational product?
IP responsibilities
What is a medical device?

Chapter 11 – Technology

Chapter 12 – Data and data governance

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
Non-compliance
End of trial, patient with-drawal or trial termination

Chapter 14 - E6 R3 appendices

Appendices: What do these include?
Appendix A: Investigator's Brochure (IB)
Appendix B: The clinical trial protocol and amendments
Appendix C: Essential records for the conduct of a clinical trial

MODULE FOUR

Summary
Exam
Accessing your certificate