ICH Good Clinical Practice Refresher (Including E6 R3)

Introducing our brand new, interactive, and engaging online GCP refresher training course, designed for individuals who have completed a full GCP course within the last two years. This course refreshes your previous knowledge while incorporating the latest ICH GCP E6 Revision 3 guidance, released on 6th January 2025, reflecting the most recent changes in the GCP framework to ensure compliance with global standards for clinical trials.

This comprehensive refresher training is perfect for those involved in clinical research who want to stay current with the latest regulatory updates and best practices. Participants will receive official GCP certification, recognised by sponsors and CROs worldwide. Created by subject matter experts with over 35 years of experience in clinical research, this course includes improved knowledge checks and interactive elements to enhance engagement and effectiveness in the learning process.

As a participant, you are responsible for ensuring your knowledge and compliance with GCP standards. Please note that while this course meets the training requirements set forth by Transcelerate Biopharma Inc., we cannot guarantee your compliance if you previously completed GCP training with another provider. This refresher course is ideal for helping you maintain compliance and stay informed about the latest developments in clinical trial standards.

The Faculty of Pharmaceutical Medicine has approved this online GCP training course for CPD points.
CPD Points Available: 4

Learning Objectives

1. Understand Key Changes in ICH GCP E6 R3
Gain a comprehensive understanding of the new principles, updates, and roles in the ICH GCP E6 R3 guidelines and their impact on clinical trials.

2. **Prepare for Implementing ICH GCP E6 R3**
Learn how to adapt and implement the updated GCP standards in your role, ensuring full compliance with the latest guidelines and enhancing trial conduct.

3. **Navigate Evolving Roles and Responsibilities**
Understand the updated roles and responsibilities for investigators, sponsors, and key stakeholders as outlined in the E6 R3 guidance.

4. **Ensure Effective Risk Management**
Develop skills to assess and manage risks in clinical trials using updated GCP risk-based approaches to ensure safety and compliance.

5. **Promote Data Integrity, Quality, and Monitoring**
Explore strategies for maintaining data integrity, ensuring high-quality practices, and applying effective monitoring techniques to enhance oversight and compliance in clinical research.

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Training Online 4U

COURSE CONTENTS:

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
Types of clinical trials

Chapter 5 – Sponsor

The sponsor

Chapter 6 – Investigator

The investigator

Chapter 7 – Monitoring

Monitoring
Monitoring visits and reporting

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 and medical devices

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

Chapter 11 – Technology

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 withdrawal 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 THREE

Summary
Scenario Learning
Exam
Accessing your certificate

Duration: 4-6 hours

Price: £120