Good Clinical Laboratory Practice (GCLP) Online Course

Course Overview

Good Clinical Laboratory Practice (GCLP) plays a critical role in ensuring the reliability of laboratory data generated during clinical trials. High quality laboratory processes support accurate safety evaluation, robust decision making, and ultimately the protection of participants.

This course provides a practical, structured introduction to GCLP principles and their application within laboratories supporting clinical research. It explores how GCLP builds on Good Clinical Practice (GCP) to ensure that laboratory activities are performed in a controlled, consistent, and quality-driven manner.

Learners will gain insight into the key components of a GCLP-compliant quality system, including organisation and personnel, facilities and equipment, sample management, analytical processes, data integrity, and quality assurance. The course focuses on how these elements work together in practice to maintain the integrity of trial data from sample collection through to reporting.

Designed with a real-world, risk-based approach, the course supports professionals in understanding their responsibilities and applying GCLP principles confidently within their roles. It is suitable for anyone involved in the handling, analysis, or oversight of clinical trial samples.

Learning Objectives

- Explain the purpose and scope of Good Clinical Laboratory Practice (GCLP) and its relationship with Good Clinical Practice (GCP)
- Describe the key components of a GCLP-compliant quality system, including roles, facilities, equipment, and processes
- Apply GCLP principles to the handling, analysis, and reporting of clinical trial samples to support data integrity and reliability
- Recognise the importance of quality assurance and risk-based approaches in maintaining compliance and supporting participant safety

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Module One:

An Introduction to GCLP

GCLP Legislation and Guidance (UK, EU and Non-EU)

Laboratory Facilities

Organisation

Personnel

Summary

Module Two:

Contracts and Agreements

SOPs and Instructions

Protocol and Analytical Plan

Equipment

Materials and Reagents

Computer Systems

Conduct of the Work:

- Sample/Material Management
- Data
- Analytical Results and Reporting

Summary

Module Two:

Participant matters:
Privacy and Confidentiality

Informed Consent and Blinding

Quality Control and Quality Assurance:
Quality Control

Quality Assurance and Audit

Archiving and Retention of Data

Duration: Approx. 4 hours. 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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