



Ensuring Compliance in Non-Clinical Laboratory Studies

Good Laboratory Practice (GLP) governs the conduct of personnel involved in the safety testing of prospective drugs, ensuring data integrity, reliability, and regulatory compliance.

This interactive and engaging course explores:

The Need for GLP – Understanding its importance in non-clinical research

Regulatory Framework – Key principles issued by the OECD

GLP Compliance in Practice – Personnel, equipment, and facilities required for adherence

Real-World Application – Workplace scenarios to reinforce learning

The course includes the latest update for 2024: The **OECD position paper on GLP and IT security** highlights the integration of IT systems and data security within GLP compliance, reflecting the ongoing evolution of GLP in response to technological advancements. It has also been recently updated to include the **new revision 3 of ICH GCP released in 2025**.

Learning Objectives

1. Understand the GLP guidelines that govern clinical trials worldwide.

Gain a comprehensive understanding of the principles, updates, and roles in the GLP guidelines and their impact on clinical trials.

2. Understand the key aspects of GLP compliance.

Focusing on maintaining data integrity, ensuring quality assurance, and effectively managing risks and deviations in laboratory studies.

3. Know the guidance and regulations surrounding GLP

Understanding how to apply the current guidance in your role.



COURSE CONTENTS:

MODULE ONE

Chapter 1: Introduction to GLP

Definition and overview of GLP
The development of GLP
Importance of GLP in laboratory settings
Key GLP principles

Chapter 2 – Regulatory Framework and Standards

Regulatory bodies
International GLP standards
Role of GLP in compliance and audits

Chapter 3 – GLP Organisation and Management

Role and responsibilities in GLP laboratories
Laboratory personnel and training requirements

Chapter 4 - Laboratory Facilities and Equipment

Requirements for laboratory design and maintenance
Equipment calibration and maintenance
Environmental controls
Health and safety Standards

Chapter 5– Test Systems and Study Design

Definition and classification of test systems
Protocols for study design and planning
Sampling methods and procedures

Chapter 6– Standard Operating Procedures

Importance and creation of SOPs
Implementing SOPs, compliance and training

MODULE TWO

Chapter 7 – Data Management and Integrity

Documentation and record keeping
Handling data corrections and amendments

Chapter 8– Quality Assurance and Auditing

Role of quality assurance
Quality assurance and GLP

Chapter 9– Safety and Risk Management

Health and Safety Protocols
Risk assessment and hazard identification
Chemical, biological and environmental safety
Personal Protective Equipment and emergency procedures

Chapter 10– Reporting and Communication

GLP compliant study reports

Chapter 11– Handling Adverse Events and Deviations

Investigating deviations and non-compliance
Corrective and Preventive Actions (CAPA)
Identifying and reporting adverse events

Chapter 12– Ethical Considerations in GLP

Ethical standards for animal and human testing
Responsible conduct in research

Chapter 13– IT security

IT security and GLP

Chapter 14– New Developments

Multi-site study management in GLP
Subcontracting in GLP
Handling of biological materials and emerging technologies

Summary
Scenario learning
Exam
Accessing your certificate

Duration: 3-5 hours

Price: £159