



BACKGROUND

The international standard of GLP or Good Laboratory Practice is a data and quality management system used to promote the quality and validity of test data. GLP has been created to guarantee the quality, consistency and reliability of data which has been generated and accumulated through laboratory studies. It embodies a set of principles (OECD, FDA, EPA) that provide a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived.

COURSE OBJECTIVES

On completing this two-day course the participant will:

- ▶ Be familiar with the principles and significance of GLP, and
- ▶ Be able to apply these principles successfully in a laboratory setting so that the laboratory in question can become GLP-compliant.
- ▶ Be able to correctly analyse, interpret and report laboratory data.

PRE-REQUISITES

None

COURSE PROGRAMME (WHAT WILL YOU LEARN?)

This course is based on the OECD GLP Principles, which are recognized as the international standard for GLP. All GLP texts, irrespective of their origin, stress the importance of the following five points:

1. **Resources.** Management, Personnel, Facilities: Buildings and Equipment,
2. **Characterization.** Test and reference items, and Test systems to which the test and reference items are to be administered,
3. **Rules.** Protocols (Study Plans), Standard Operating Procedures (SOPs),
4. **Results.** Raw data, Final Report, Archives,
5. **Quality Assurance.** Audit/ Inspection, Training, Advice.

Each of these five points will be discussed in detail during the course as they relate to GLP.

Analysis of laboratory data will include calculation of measurement uncertainty and statistical analysis.

Similarities and differences between GLP and the international standard ISO/IEC 17025:2005 used in the accreditation of commercial testing and calibration labs will be discussed.

Throughout the course, worked examples and practical case studies will be used to help delegates apply GLP requirements and responsibilities with regards to personnel, facilities, equipment, test systems and record storage.

COURSE E-BOOK, REFERENCE MATERIAL & MANUAL

A comprehensive e-workbook provides practical examples and supplementary reading while reference materials provide additional information for improving your legal knowledge. The course manual contains copies of the course presentation slides and case studies.

WHO SHOULD ATTEND?

Laboratory Managers/Supervisors, Analysts, Technicians, Research Scientists, Post-graduate Students, Quality Assurance staff, Auditors, Technology Transfer Officers, and anyone who wishes to increase their understanding of Good Laboratory Practice.