



Principles of Good Laboratory Practices

This course provides the basic understanding of cGMP's that are required for Good Laboratory Practices (GLP). It will review the current terminology and regulations required for complying with GLPs. The course will include a discussion of the functions and roles of the quality assurance unit, study director and clinical personnel. The documentation that is required as well as the need for accurate recording of raw data results and record keeping for inspections will also be examined.



Who Should Attend: laboratory technicians, managers, scientists and engineers.

Class Length: 1 day

Maximum Class Size: 20

Course Prerequisites: None

Course Objectives: At the conclusion of the class a participant will have an understanding of the following:

- The history of Good Laboratory Practices (GLP)
- Basic GLP terminology
- Regulatory agencies involved with GLP's
- What the FDA is and its role in the regulated industries
- Where the cGMPs and GLPs are written and which ones apply
 - o 21 CFR part 58 Good Laboratory Practices for non-clinical laboratory studies
 - o 21 CFR part 11 Electronic Records; Electronic Signatures
 - o 21 CFR 210 and 211 In Manufacturing, Processing, Packing, Or Holding Of Drugs
- The compliance requirements for the different job functions found in a GLP setting
 - o The role of the manager
 - o The responsibilities of the technician
- Facility requirements
- Critical documents
 - o Which ones are required?
 - o How should they be maintained and how long?
- Regulatory requirements for activities performed in the laboratory such as study plans, protocols, training, documentation, instrument usage, calibration, validation, record keeping, documentation of deviations and testing methods
- The GLP employee's role in an FDA inspection
- The FDA's options for enforcing compliance with the regulations
- How to manage laboratory reagents and samples

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