Basic Training: Good Laboratory Practice

By the end of each module you’ll be able to accomplish the following objectives:

Module 1: History of GLPs
• List key developments in U.S. federal regulations of medicinal products prior to the establishment of Good Laboratory Practices
• Describe the reasons for the federal government’s investigation of G.D. Searle, a drug manufacturer, and how it led to the development of specific FDA GLPs
• Describe the findings of the FDA’s investigation of Industrial Bio-test Laboratories and Biometric Testing, Inc. and how they, too, led to the development of the FDA GLPs
• List the outcomes of these investigations

Module 2: Subpart A – General Provisions
• Define key terms from the GLP regulations
• Identify the components of a nonclinical laboratory study as defined by the FDA GLP regulations
• List some differences in the scope of the FDA’s GLP regulations versus the EPA’s GLP regulations
• Identify the Sponsor’s and service provider’s responsibilities associated with performance of studies under FDA and EPA GLPs
• Describe the FDA’s and EPA’s authority in inspecting testing facilities

Module 3: Subpart B – Organization and Personnel
• List the roles and responsibilities of:
  o Nonclinical laboratory study personnel
  o Testing Facility Management
  o Study Director
  o Quality Assurance Unit
• Recognize and identify where the regulatory requirements concerning these roles and responsibilities are not being met

Module 4: Subpart C – Facilities
• Identify general requirements for test facilities
• Identify characteristics of compliant and noncompliant animal care and supply facilities
• Identify regulatory requirements for handling test and control articles
• Identify minimum requirements for laboratory operation areas
• Identify requirements for data and specimen storage facilities

Module 5: Subpart D – Equipment
• Identify the regulatory requirements for equipment use in a GLP study
• Identify documentation required in support of the use of equipment in a GLP study
• Determine if equipment documentation meets the requirements of this part of the regulation
Module 6: Subpart E (Part 1) – Testing Facilities Operation
- Explain why SOPs are necessary for regulated studies
- Identify the regulatory requirements for SOPs
- Determine which types of SOPs are necessary for GLP studies
- Identify personnel who should write, review and authorize SOPs
- Identify regulatory requirements for reagents and solutions

Module 7: Subpart E (Part 2) – Testing Facilities Operation: Animal Care
- Identify the SOPs necessary for the conduct of studies using animals
- Identify requirements for animal health prior to use in nonclinical studies
- Identify requirements for animal identification and housing
- Determine the requirements for the use of equipment and/or supplies in nonclinical studies
- Identify the regulatory requirements for animal care

Module 8: Subpart F – Test and Control Articles
- Indicate why test and control articles should be characterized
- List the regulations in Section 58.105 regarding test and control article characterization
- List the regulations in Section 58.107 regarding test and control article handling
- Indicate why test and control article mixtures are required to be analyzed and who is responsible to ensure this testing is performed
- List the regulations in Section 58.113 regarding mixtures of articles with carriers

Module 9: Subpart G (Part 1) – Protocols for Nonclinical Studies
- Describe what a nonclinical study protocol is
- Identify the regulatory requirements for the content of a nonclinical study protocol
- Explain why a protocol is necessary for a nonclinical study
- List the requirements for protocol changes and deviations

Module 10: Subpart G (Part 2) – Conduct of a Nonclinical Laboratory Study
- Explain why the regulations were promulgated with respect to study conduct
- Identify the requirements for conducting nonclinical studies
- Identify the characteristics of quality data, both manually collected and data collected by automated systems
- List appropriate practices for the recording and handling of data

Module 11: Subpart J – Records and Reports
- Identify reasons why the regulations were promulgated with respect to reporting of nonclinical study results
- Identify the requirements for the reporting of nonclinical study results
- Identify the reporting requirements for different report types
- Identify the requirements for reporting compliance exceptions
- Identify the requirements for storage and retrieval of data and reports for nonclinical studies
- Determine required record retention periods for FDA and EPA study materials