# 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:
    - Nonclinical laboratory study personnel
    - Testing Facility Management
    - Study Director
    - 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