



## **GLP Study Director and Principal Investigator Training**

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

### ***Module 1: History and Introduction to GLPs***

- Describe the difference between GLP regulations and principles
- Be aware of prominent cases that prompted the establishment of the GLPs
- Identify the difference in scope between the U.S. FDA GLPs, the EPA GLPs, and the OECD GLPs

### ***Module 2: Roles, Responsibilities, Multi-site Studies***

- List the GLP responsibilities of the Study Director, Principal Investigator and Quality Assurance, including multi-site studies
- Identify the OECD GLP documents where requirements for multi-site studies can be found and the SOPs OECD recommends for such studies
- List issues specific to multi-site studies

### ***Module 3: Types of Studies, Facilities, Animal Care***

- Determine if a study falls under the requirements of a GLP study
- List GLP requirements for study facilities, including those housing research animals

### ***Module 4: Equipment***

- Identify equipment that falls under the requirements of a GLP study
- Determine if equipment is fit for use in a GLP study
- Differentiate routine and nonroutine maintenance of equipment

### ***Module 5: Test Materials***

- Identify FDA, EPA and OECD GLPs terminology for test materials
- List ways test materials are required to be characterized
- List labeling, handling, storage and documentation requirements for test materials
- Describe the importance of test material mixtures and how dose is determined

### ***Module 6: Conducting a Study***

- Determine if a study protocol contains the regulatory requirement elements
- Identify different types of data that fit the definition of "raw data"
- Record and correct entries in compliance with GLP regulations and standards
- Define the terms "protocol amendment," "deviation," and "unforeseen event"

- Explain the importance of study reconstructibility

***Module 7: Study Quality and Reporting***

- List the types of inspections and audits, both internal and external, that occur with most GLP studies
- List ways the Study Director can ensure an audit or inspection is successful
- Given a final study report, determine if its contents meet the requirements of the GLPs
- Determine how long study materials must be retained in archives
- List the possible consequences of failing to comply with regulated GLP studies