COBBLESTONE

COURSE ID 2970

Basic FDA GLP Training

Good Laboratory Practice Training

DIRECTED BY

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2 HOUR

ACCREDITED COURSE

Course Topics Include:

- History, Intent, Scope of the FDA GLP Regulations
- Specific FDA GLP Requirements and Associated Predicate Rules
- Proposed Revisions to the FDA GLP Regulations

about the course

Before any drug can be used on humans, it must first be proven to be safe through testing on animal models. The FDA Good Laboratory Practice (GLP) regulations were implemented in 1979 in response to the inadequate quality and scientific rigor of nonclinical (toxicology) studies. The FDA GLPs outline the requirements for conducting nonclinical studies that adhere to FDA expectations and encompass bioanalytical analyses for GCP-regulated studies. The FDA GLPs were revised in 1987 and, more recently, revisions have been proposed to refine these regulations to reflect current industry practices

This two-hour training session is accredited and aims to provide a fundamental understanding of the FDA GLP Regulations. The lecture will cover the history, purpose, scope, and requirements of the GLPs and other associated rules. By comprehending these regulations, professionals responsible for nonclinical studies can ensure that their work is carried out in accordance with the FDA's guidelines, leading to the protection of human subjects' health and safety. Real-life examples and activities will be incorporated into the training to enhance the learning experience.

who should attend

Basic FDA GLP training is applicable to the various industries and functions that perform nonclinical laboratory studies under FDA GLP regulations. The Basic FDA GLP Training will be valuable to all individuals working in the animal health, biologics, device, and pharmaceutical industries including:

- New Quality Assurance Auditors
- Quality Assurance Auditors and Managers as refresher training or as GLP skill development
- Quality Assurance Directors as refresher training or as GLP skill development
- Scientists performing GLP-regulated studies
- Laboratory Personnel conducting bioanalytical analyses for GCP-regulated studies

This training is geared toward study management as well as scientific and quality professionals responsible for FDA GLP-regulated activities.

learning objectives

Upon completion of this course, you will be able to:

- Explain the history, intent and scope of the FDA GLPs
- Apply the specific requirements of the FDA GLPs and related predicate rules
- Recall the anticipated revisions to the FDA GLPs

course outline

Review of Learning Objectives
Module 1

- History
- Scope
- Definitions
- Predicate Rules

Module 2: Subparts of the GLPS

- Organization and Personnel
- Facilities
- Equipment
- Testing Facilities Operation
- Test and Control Articles
- Protocol and the Conduct of a Nonclinical Laboratory Study
- Records and Reports
- Disqualification of Testing Facilities

Module 3: Proposed Revisions to the GLPs

- Sponsor Responsibilities
- Quality System Approach
- Use of Multi-sites

Summary

Question and Answer Session

Assessment Opportunity

course instructor

Bonnie M. Pappacena is the President, Qualture LLC, a Quality consulting firm committed to building Quality into company culture.

Ms. Pappacena has been a Quality professional for over 35 years spanning the animal health, biological, chemical, gene therapy, device, generic, and pharmaceutical industries. She possesses hands-on experience conducting and managing audits in GCP, GLP, GMP (clinical supplies and commercial products), and GVP regulated areas. She is well versed in building quality teams to provide independent, effective quality oversight for regulated areas.

Prior to establishing Qualture LLC, Ms. Pappacena was Vice President, Quality at Foamix Pharmaceuticals. She also held the position of Vice President Quality at G&W Laboratories and Acorda Therapeutics. Ms. Pappacena was also employed as a Quality professional while at Schering Plough, Lederle, SmithKline Beecham Animal Health, and Monsanto.

Accreditations

International Accreditors for Continuing Education and Training (IACET)
Cobblestone has been approved as a CEU Accreditor by IACET and awards CEUs for participation in qualified courses. Cobblestone has demonstrated that it complies with the ANSI/IACET Standards and is authorized to offer IACET CEUs for its programs. CEUs will be awarded for participation in Cobblestone's courses at the rate of .1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment. A minimum score of 80% is required for all courses within a Cobblestone Certification Program. This course offers a total of 2 contact hours, or .2 CEUs. For further information, visit www.iacet.org

Regulatory Affairs Professional Society (RAPS)
Cobblestone is committed to enhancing the ongoing professional development of regulatory affairs professionals and other stakeholders through appropriate regulatory affairs learning activities and programs. Cobblestone has agreed to follow RAPS- established operational and educational criteria. This course may be eligible for up to 12 credits towards a participant's RAC recertification upon full completion. The requirements and standards for recertification are developed and administered by the Regulatory Affairs Certification Board (RACB), which manages all areas of the RAC program. Additional information about RAC is available on the RAPS website at RAPS.org/rac.