COBBLESTONE

COURSE ID 2877

Good Laboratory Practice for Nonclinical Laboratory Studies

DIRECTED BY

Lucia Mokres — Consultant to the Biotechnology Industry

90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- Origin of Good Laboratory Practice
- Current guidance
- Nine major sections of GLP regulation

about the course

Complying with the principles of Good Laboratory Practice for Nonclinical Laboratory Studies (GLP) is of utmost importance to ensure the reliability and credibility of study data. Nonclinical laboratory studies, also known as preclinical studies, play a vital role as a prerequisite for demonstrating the safety and essential performance aspects of products intended for human use.

In this 90-minute accredited course, we will delve into the origins of GLP, thoroughly examine its key components, and present insightful case studies that allow participants to analyze and develop strategies for addressing GLP-related situations that may arise within their organizations. Furthermore, we will explore the circumstances under which non-GLP studies may be deemed appropriate, providing participants with a comprehensive understanding of when alternative approaches can be considered.

who should attend

This course is intended for all industries developing products that require FDA approval for research or marketing including food and color additives, animal food additives, human and animal drugs, medical devices for human use, biological products, and electronic products. It will be beneficial to anyone planning, conducting, monitoring, managing, supervising, or otherwise supporting non-clinical studies. This program is especially valuable for onboarding any employee involved directly or indirectly in nonclinical study planning and execution, to ensure alignment on GLP culture and fundamentals within your organization prior to engaging in work that impacts GLP compliance.

learning objectives

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

- Recount the origin of Good Laboratory Practice and where to find current guidance
- List the 9 major sections of the FDA GLP regulation and describe key elements of each
- Evaluate case studies pertaining to GLP and consider what you would have done differently
- Determine when non-GLP studies might be appropriate

course outline

Review of Learning Objectives
Module 1

- Walk through of the events that led to GLP
- The impact on the conduct of nonclinical research
- Quiz and Review

Module 2

- Review of the 9 major sections of GLP regulation
- Quiz and Review

Module 3

- Case Studies
- When is non-GLP appropriate?
- Quiz and Review
- Summary

Question and Answer Session

course instructor

Dr. Lucia Mokres, is a Life Science Consultant based in the San Francisco Bay Area. She specializes in coaching early-stage companies through Stakeholder Ecosystem Discovery, allowing them to gain traction and develop an investable technology and business model. She also loves rolling up her sleeves to help companies at all stages meet urgent medical, regulatory, and clinical project deadlines, leveraging her broad experience and expertise to rapidly produce high quality deliverables. She is a member of OccamPoint, a consortium of consultants providing due diligence support for investment and M&A activities. Prior to establishing her consultancy, she was the Chief Medical Officer of EpiBiome, Inc. In this role she provided medical oversight and strategic direction for clinical development activities, defined regulatory strategy, and supported marketing and business development activities. She led EpiBiome through the NSF Innovation Corps and several other accelerator and mentoring programs, and was an invited speaker nationally and internationally on the challenges faced by early-stage companies seeking product approval or clearance. Prior to joining EpiBiome, Dr. Mokres served as a clinical scientist and medical advisor in the medical device industry. She completed her postdoctorate at Stanford University School of Medicine and graduated from the Colorado State University College of Veterinary Medicine and Biomedical Sciences.

In her spare time, Dr. Mokres mentors other early-stage companies through the Springboard Enterprises, MassCONNECT, National Science Foundation Innovation Corps, and California Life Sciences Institute FAST Advisory programs; and mentors women completing their PhD and postdoctoral studies on behalf of the Association for Women in Science.

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 1.5 contact hours, or .2 CEUs. For further information, visit www.iacet.org