Good Laboratory Practice for Nonclinical Laboratory Studies

Course ID # 2877

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 training, 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 description

Adherence to Good Laboratory Practice for Nonclinical Laboratory Studies (GLP) is critical for ensuring the quality and integrity of study data. Nonclinical laboratory studies (sometimes referred to as preclinical studies) are crucial, and prerequisite, for demonstrating the safety and key aspects of performance of products intended for human use. In this 90-minute accredited course we will discuss the origin of GLP, review the major components of GLP, consider case studies that allow participants to examine how they would handle GLP-related situations if confronted with them in their organization, and 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

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course director

Lucia Mokres, Consultant to the Biotechnology Industry

Dr. Lucia Mokres is a Biotechnology Entrepreneurial Consultant based in the Bay Area, specializing in helping early stage companies with novel technology gain traction and develop an investable technology and business model, and helping later stage companies work through regulatory and clinical challenges. Prior to establishing her consultancy, she was the Chief Medical Officer of EpiBiome, Inc., a precision microbiome engineering company that employs a genomics approach to profiling complex microbial communities, and deploys bacterial viruses to selectively eliminate problematic bacteria without the use of small-molecule antibiotics in humans, animals, and plants. In this role she leveraged her clinical, research, and industry background to provide medical oversight and strategic direction for all clinical development activities, defined regulatory strategy, supported marketing and business development activities, and served as the medical point of contact for external stakeholders. Prior to joining EpiBiome, she served as a Principal Clinical Scientist and medical advisor at Evolve (acquired in 2010 by Abbott Vascular), supporting medical safety and development of the MitraClip, a minimally invasive device used to reduce mitral regurgitation without the need for open heart surgery. Prior to joining Evolve, she served as a Program Specialist at Hantel Technologies, a contract medical device engineering and manufacturing firm, serving as a liaison between clients and internal departments, and managing timelines and budgets for projects ranging from single person startups to Fortune 500 companies. She completed her postdoctoral fellowship at Stanford University School of Medicine in the Department of Pediatrics.

In her spare time, she instructs a Stanford Medical School elective, which provides training for medical students, nurses, physicians and other healthcare professionals in bedside manner, teamwork, leadership, and nonverbal communication skills; serves on the Association for Women in Science STEM to Market Advisory Board; is a member of the AWIS Palo Alto Mentoring Committee; and mentors other early stage companies through the Springboard Enterprises and California Life Sciences Institute advisory programs.

She completed her postdoctoral fellowship at Stanford University School of Medicine in the Department of Pediatrics, and graduated Cum Laude with a Doctorate in Veterinary Medicine from Colorado State University College of Veterinary Medicine and Biomedical Sciences.

tuition and registration

TUITION– Single Rate: U.S.$295.00 per person      Group Rate: U.S.$245.00 per person

Register at www.cfpa.com. Enter Course ID# 2877 into Search. To register click Register Now.

For Questions and Information call Customer Service at 732-613-4500.

Please Note: Multiple participants are not authorized to share access provided to a single registrant, a single dedicated seat license must be purchased for each individual. CfPA reserves the right to cancel access or collect the group rate payment if this requirement has been violated. Only registered participants will receive accreditation.

accreditations/recertifications for this course

The Center for Professional Advancement has been approved as an Accredited Provider by the International Association for Continuing Education and Training (IACET), 2201 Cooperative Way, Suite 600, Herndon, VA 20171. In obtaining this approval, The Center for Professional Advancement has demonstrated that it complies with the ANSI/IACET Standards which are widely recognized as standards of good practice internationally. The Center for Professional Advancement is therefore authorized to offer IACET CEUs for its programs that qualify under the ANSI/IACET Standards. CEU will be awarded for participation in The Center for Professional Advancement’s courses at the rate of .1 CEU per contact hour. CEU will be awarded only upon successful completion of the entire course and 70% accuracy in the required Learners’ Assessment. This course offers a total of 1.5 contact hours or .2 CEUs (CEUs rounded up).

we also offer

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Online Training: A convenient and cost-effective way to experience our accredited training. Easily access the knowledge you need through the Internet. For a list of upcoming courses visit www.cfpa.com/onlinetraining

Virtual Attendee: Ideal for those who need the training but cannot attend in person. For more information visit: www.cfpa.com/virtualattendee

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