COBBLESTONE

COURSE ID 2876

Good Clinical Practice: When Good Studies Go Bad

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- Origin and evolution of Good Clinical Practices
- Sources for GCP guidance
- Key elements of GCP

about the course

The concept of Good Clinical Practice (GCP) goes beyond a mere collection of guidelines and complex, challenging language to interpret. It encompasses the culmination of years of progress and revelations in the field of medicine, encompassing both well-intentioned and misguided human decisions, along with consequences that range from unfortunate to truly horrifying. GCP serves as a formalization of the invaluable lessons we have learned throughout our relentless efforts to diagnose, treat, and prevent illnesses and injuries. It represents our current best comprehension of how to strike a balance between the advantages of introducing groundbreaking medical products to the market and the inherent risks associated with experimentation.

In this 90-minuted accredited course, participants will delve into the historical context of GCP, gaining insight into the resources available and how to effectively implement GCP within their respective organizations. Moreover, the course will explore hypothetical scenarios related to GCP, allowing participants to examine and refine their approach to handling such situations.

who should attend

This course is intended for professionals in all life science industries using human subjects in investigation. It will be beneficial to anyone planning, conducting, monitoring, managing, analyzing, or otherwise supporting human clinical trials. This program is especially valuable for onboarding any employee involved directly or indirectly in clinical trial planning and execution, to ensure alignment on GCP culture and fundamentals within your organization prior to engaging in work that impacts GCP compliance.

learning objectives

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

- Recount the origin of Good Clinical Practice and explain how and why it evolved over time
- Identify sources for Good Clinical Practice guidance, summarize key elements, and determine which apply to your specific product
- Evaluate case studies pertaining to GCP and consider how you would handle them

course outline

Review of Learning Objectives
Module 1: Good Clinical Practice: Why

- Historical events that led to GCP
- Their impact on the conduct of clinical research

Quiz and Review

Module 2: Good Clinical Practice: Where, What, How

- Where to find GCP materials
- Key elements of GCP
- Interpreting GCP in the context of your medical product

Quiz and Review

Module 3: Good Clinical Practice: Who and When

- Case Studies: What Would You Do?
- Quiz and Review
- Summary

Question and Answer Session

Assessment Opportunity

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