COBBLESTONE

COURSE ID 2842

GXP Foundations

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- How and Why GXP
- GXP Principles
- GXP and YOU Case Studies

about the course

GXP represents a collection of regulations and guidelines that encompass best practices for various crucial aspects of medical product development. Due to the intricate regulatory environment and the distinctiveness and diversity of medical product innovations, it can be challenging for sponsors to establish a framework for product development and marketing that satisfies regulatory requirements while accommodating the unique needs of the product.

Apart from ensuring compliance and obtaining regulatory product approval, GXP can also serve as a philosophy for fostering a thriving and effective corporate culture throughout the lifespan of a company, from its establishment to its eventual exit.

This 90-minute accredited training session will focus on essential components of GXP and provide insights into its implementation.

who should attend

This course is intended for professionals within all branches of the regulated medical product sector, including Pharmaceuticals, Biologics, Diagnostics and Medical Device industries. Personnel from entry-level to executive performing in the following positions will find the course valuable:

Clinical: Research Associates, Scientists, Study and Site Monitors, Data Specialists, Trial and Operations Managers
Preclinical: Study Scientists, Technicians and Managers
Quality: Engineers, Associates and Managers
Regulatory: Regulatory professionals, whether you are just learning GXP or are senior level and need a refresher, will find this course useful.
Manufacturing: Technicians, Assembly, Engineers, and Supervisors; Shipping/Receiving
Engineering/R&D: Engineers at all levels, Scientists at all levels
Executive Leadership, especially if you are new to medical product development; are in need of a GXP refresher; or are leading an early-stage company and want to establish a quality-oriented corporate culture

learning objectives

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

- Define GXP
- Outline some of the key GXP related to medical product development
- Describe common elements of GXP
- Explain in general terms how and why GXP is implemented
- Develop a corporate culture driven by GXP principles
- Articulate the importance you play in your company, regardless of role
- Establish a healthy, productive work environment

course outline

Review of Learning Objectives
Module 1: GXP Overview

- GXP Defined
- Overview of the following GXP:
    - GCP
    - GLP
    - cGMP
    - GDocP
    - GDP
    - GVP

Module 2: GXP: The How and the Why

- Discussion: What are the common elements of the GXPs discussed in Module 1?
- Key elements of GXP
- How GXP is implemented
- GXP as a risk mitigation strategy

Module 3: GXP and YOU

- Individual responsibility for GXP
- GXP and corporate culture
- 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 accelerators 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 post doctorate 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

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.