COBBLESTONE

COURSE ID 2940

Managing Standard Operating Procedures (SOPs) in the FDA Regulated Environment

GMP Laboratory Control Professional Certification Program

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- FDA's Expectations
- Effective and Efficient Documents
- Control, Archival & Disposal
- Checklists
- Authors' and Reviewers' Roles

about the course

Standard Operating Procedures (SOPs) are a regulatory requirement for industries that are governed by the FDA and other world health authorities. Currently, there is no guidance on how to develop or manage the SOP creation or the SOP quality system. Consequently, SOPs are frequently written in a way that makes compliance difficult or downright impossible. In many cases, this sometimes leads to subpar documents that come to light during a regulatory inspection.

In this 90-minute accredited training, you will learn how to write, organize, and maintain SOPs and train personnel in a method that will ensure compliance in a way that is reproducible and easy to follow.

This training will cover such topics as:

- Why written procedures are beneficial
- FDA expectations for written documents and Regulatory Requirements
- Developing an effective review and approval process compliant with regulatory requirements
- How to implement a training program for document creation and review
- A system for the control, archival, and disposal of written procedures

This training is one part of the 10-course series required for the GMP Laboratory Control Professional Certification Program.

Attend this as a step in the certification process or as a stand-alone course for personal career advancement and training

who should attend

This training has been designed to benefit professionals in the FDA-regulated industries including pharmaceutical, medical devices, biotechnology, cosmetics, and food.

It will be especially valuable to those Directors, Managers, Professionals, Technical writers, and General staff charged with the responsibility for creating, reviewing, and approving written standard operating procedures and instructions.

learning objectives

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

- Describe the steps in formatting SOPs
- List elements to include other than the procedure
- Explain how to write effective but efficient documents
- Describe the roles and responsibilities of authors and reviewers of SOPs
- Define roles in SOPs for supervisors and operators

course outline

Review of Learning Objectives
Module 1: Standard Operating Procedures Defined

- Regulatory requirements
- Key Definitions

Module 2: Benefits of a Compliant SOP System

- Customer service
- Training documents
- Checklists

Module 3: Plan for Results

- Process map for a first draft
- Conducting an internal and external review
- Testing, posting and auditing the finished product

Assessment Opportunity

course instructor

Danielle DeLucy, MS, is currently the owner of ASA Training & Quality Consulting, LLC, an Independent Consultant Agency to the Biologics and Pharmaceutical Industries specializing in the areas of Quality Assurance and Quality Systems. Prior to this role, Danielle has been in the industry for 18 years serving in numerous Quality Management Roles, such as the Director of Product Quality, the oversight of Sterility Assurance practices, and provided QA oversight of numerous filling and packaging operations.

Danielle began her QA career as a Quality Control Pharmaceutical Microbiologist at a contract laboratory where she performed various tests for their clients. In the years after, she has held positions in the Quality management arena while increasing her responsibility. She has helped to lead many Regulatory Health Inspections and was instrumental in the coaching process of her peers prior to any inspection. Currently, Danielle assists companies who are faced with warning letters and consent decrees establish more robust quality systems so that the company can succeed.

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.