COBBLESTONE

COURSE ID 3020

Managing Effective Regulatory Inspections and 483 Responses

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- Regulatory Inspection Management
- Appropriate 483 Responses

about the course

The purpose of a regulatory inspection is to ensure that your facility is in compliance with FDA rules and regulations. Investigators want to know that product was manufactured appropriately and that the current Good Manufacturing Practices are up to FDA standard. An inspection can be very intimidating to all involved, but it is vital if you want an inspection that results in a satisfactory report. Many times, the arrival of a Regulatory Investigator is a daunting experience for some.

In this 90-minute accredited course, you will learn how to properly alert key members that an investigator has arrived, the proper protocol for setting up the Inspection room and any associated "war" rooms that will support the inspection, and how to manage requests from the investigators in a timely and accurate manner. This preparation minimizes stress and disorder during the inspections.

This training is one part of the 10-course series required for the FDA Inspection Readiness 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 course will be valuable to all individuals working within or managing a manufacturing program that supports either the R&D development of a new drug product or the manufacture of commercial drug product released to the market and would be beneficial to professionals in:

• Quality Control	• Quality Assurance
• Contract Manufacturers	• Manufacturing and Filling Operations
• Technical Operations	• Research & Development

Regulatory affairs personnel as well as individuals who are responsible for the review or audit of such inspections and reports would likewise find this course very worthwhile.

learning objectives

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

- List pre-planning and preparation activities
- Describe what to do when the investigator arrives
- Discuss the Pre-Approval Inspection Compliance Program 7346.832
- Prepare the necessary documents to have on hand
- Develop assignments and responsibilities for the inspection
- List important inspection Do's and Don'ts

course outline

Review of Learning Objectives
Module 1: FDA Inspections 101

- Unannounced FDA visits – how to prepare and react
- Preparing for FDA audits / PAI preparation – what training should look like for key players
- Basic concepts that should be employed by everyone regulated by the FDA – review of quarterly quality topics to keep current

Module 2: Company Preparedness

- How a company can prepare for situations like this – training of SMEs and beyond
- How a company can balance the need to prepare for a potential FDA investigation or enforcement action and still run a profitable business

Module 3: Observations and Lessons Learned

- How should a company respond to 483 observations or a warning letter – deadlines, tracking, and closures
- Lesson learned – reviews of the observations and overall inspection

Module 4: Real Life Situations

• Case Scenarios – review of real-life scenarios that you could encounter during inspections

Assessment Opportunity

course instructor

Danielle DeLucy, MS, is currently an Independent Consultant 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 20 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.