COBBLESTONE

COURSE ID 4

# FDA Inspection Readiness Certification

A 10 Part Program

DIRECTED BY

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15
Hours

ACCREDITED COURSE

- 10 courses
- 90 minutes each

## 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. This is why it is important to 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.

Working in a highly regulated industry, we know our firms need to be inspection-ready at all times. This is not only to maintain a good rapport with the Regulators, but also as a commitment to quality for our customers, the patients who use the products.

Regulatory inspections should be a time to demonstrate the high level of compliance your firm has committed to the regulations, and to customer safety and quality.

Cobblestone's 10-Part FDA Inspection Readiness Certification program provides the key principals and tools required to become a FDA Inspection Professional. It is designed to provide rules, tools and techniques for effective and compliant management of FDA Regulatory Inspections. This FDA Inspection Readiness Certification Program offers professionals the proper training and skill development needed to attain their certificate of accomplishment.

## who should attend

The FDA Inspection Readiness Certification 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 products released to the market. Obtaining the certification would be beneficial to professionals in:

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

Regulatory affairs personnel as well as individuals who are responsible for the review or audit of such inspections and reports should likewise consider the value of this comprehensive certification in their positions.

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## learning objectives

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

- Develop Pre-planning and preparation activities.
- Know what to do when the investigator arrives.
- Know what documents to have ready and on hand.
- Understand the quality systems that will be reviewed.
- Develop assignments and responsibilities for the inspection.
- Understand inspection Do's and Don'ts.
- Develop solid and compliant responses to observations.

## certification outline

- Implementing a Change Control Quality System Successfully
- Applying Quality Risk Management
- CAPA: Definition, Plan and Program
- Data Integrity
- Complaint Handling Requirements (US)
- Best Practices for Investigation Deviations and Non-Conformances
- FDA Case Scenarios: Best Practices for Managing Inspection Situations
- Conducting Successful Quality Audits
- Capturing Justifications in Change Control, Risk Assessment, Validations, and Investigations
- Managing Effective Regulatory Inspections and 483 Responses

## 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 15 contact hours, or 1.5 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.