COBBLESTONE

COURSE ID 2923

FDA Inspection Essentials

Key Dos and Don’ts

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- Pre-Approval Inspection
- Unannounced Visits
- Warning Letters
- Documentation Requirements
- Case Studies
- Training of Key People

about the course

The purpose of the Regulatory Inspection is an activity that should demonstrate that your company is operating according to the proper CFR requirements and maintaining a state of compliance. The key to a successful audit is being able to communicate how your quality systems assure this state of control.

Many times, the arrival of a Regulatory Investigator is a daunting experience for some. In this accredited, online 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.

who should attend

This accredited 90-minute training is essential background information for anyone who will interact with FDA during an inspection. Learning what to do and what not to do will improve inspection outcomes and this gained knowledge will be particularly beneficial to professionals in the following areas:

- Quality Control
- Manufacturing
- Regulatory Affairs
- Quality Assurance
- Senior Management

Managers and supervisors of these personnel will also benefit from this training by learning about the challenges faced by them.

learning objectives

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

- Explain Pre-planning and preparation activities
- Outline What to do when the investigator arrives
- Summarize What documents to have ready and on hand
- Develop Assignments and responsibilities for the inspection
- Translate Inspection Dos 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 experience

Module 4: Real Life Situations

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

Question and Answer Session

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.