COBBLESTONE

COURSE ID 2792

Laboratory Controls: Anticipate the Systems-Based FDA Inspection

GMP Laboratory Control Professional Certification Program

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- Systems-based Inspection
- Preparing for the Laboratory Audit
- Current Trends in 483 Observations

about the course

Many QA and QC personnel in the pharmaceutical industry are not familiar with the FDA systems-based inspection model. They are also not aware of the types of 483 observations that many FDA auditors make today. One of the most scrutinized areas during these inspections is the laboratory. Because of this, it is important for lab personnel to know the techniques used the FDA inspections during these types of audits. Knowing the systems, the FDA will look at is also key so that the lab can be properly prepared for the audit.

In this 90-minute accredited training, we will discuss laboratory controls. It will focus on all of the systems that are in a laboratory that will be audited by an FDA inspector in a typical systems-based inspection. After this webinar, you will fully understand how to prepare your laboratory for the FDA.

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 online training course is intended for professionals in the Pharmaceutical and related life science industries. It will be especially valuable to:

• Quality Control Personnel & Management	• Regulatory Affairs Personnel & Management
• Manufacturing Personnel & Management	• Quality Assurance Personnel & Management
• Senior Management	

learning objectives

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

- List what makes up a Laboratory Control System
- Discuss the responsibilities of the QC and QA personnel before and during the audit
- Review the known high-risk areas to assess the level of compliance in your own laboratories
- Improve and develop systems and procedures that will sustain a compliant laboratory operation

course outline

Review of Learning Objectives

Module 1: Defining the Systems Based Inspection

- What are Lab Controls?
- FDA inspection techniques
- Why FDA switched to Systems based Inspections

Module 2: Preparing for a Laboratory Audit

- Training of analysts in proper inspection behavior
- Review of materials, equipment, tests and assays

Module 3: Inspection Expectations and Results / Real-Life citations

- Responsibilities of QC / QA personnel during the audit
- Addressing observations or findings
- Real-life citations

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.