COBBLESTONE

COURSE ID 3016

Best Practices for Investigation Deviations and Non-Conformances

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- Regulations pertaining to deviations
- How to write deviations

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.

One of the most common FDA 483 and Warning Letter citations continues to be inadequate investigations. The FDA uses the investigation reports and investigation trends to identify potential quality problems in all areas of the company. Ultimately, inadequate investigations can lead to 483 citations, Warning Letters, release of sub-standard product, or product recall. Furthermore, costly and time-consuming system remediation may be required. Having a procedure on deviation investigations is not enough. It is the content and conclusions of the investigations themselves that truly count. Doing a proper root cause analysis, gathering evidence and ensuring a sustainable corrective action is key to a proper deviation investigation.

This 90-minute accredited course will help attendees understand the fundamental investigation steps and skill sets. Key focus will be placed on identification and initial reporting of deviations, fact/evidence gathering, and arriving at the correct root cause and CAPA. The importance of investigation planning, critical thinking skills and effective preventative action plans will also be discussed.

This training is one part of the 10-course series required for the Cobblestone 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:

- Discuss what to do when problems occur
- Outline the requirements of the deviation and procedure including the deviation report
- Choose the most appropriate root cause analysis methods for the situation
- Discuss how to conduct the deviation and the tools to be used in the process
- Review and discuss an example deviation using the tools suggested

course outline

Review of Learning Objectives
Module 1: Review of FDA and Regulatory Requirements for Investigations

- FDA and EU Requirements

Module 2: How to Handle a Complaint

- Types of Deviations
- Identification of Deviations
- Classifications of Deviations

Module 3: Conducting the Investigation

- Interviews – dos and don'ts
- Source Documents/Evidence

Module 4: Determining Root Cause and Corrective/Preventative Action

- Methods of Root Cause
- Differences between corrective and preventative actions

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.