COBBLESTONE

COURSE ID 3015

Complaint Handling Requirements (US)

Interrelationship with CAPA, Change Control, Adverse Event Reporting, Recalls and Life Cycle Process Activities.

DIRECTED BY

Danielle DeLucy — MS, Independent Consultant to Biologics & Pharmaceutical Industries Quality Assurance Specialist

90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- Customer Complaints
- Recalls
- Adverse Events

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.

The FDA consistently has focused on complaints as part of post market surveillance. Numerous citations are related to deficiencies and lack of implementation or effective implementation of complaint handling activities, documentation, and the disconnect between complaints with CAPA/change control/adverse event reporting/recalls. Regulated companies don't always establish and implement a unified approach to these regulated systems.

This 90-minute accredited course is intended to help you better understand and get familiar with the requirements for complaint files and key requirements of:

- Complaint procedures
- Investigations
- What to document when it is determined that an investigation is not needed
- What actions are required if a complaint represents a reportable event
- Record retention

In addition, the course will incorporate the complaint handling life-cycle process and an example of activities involved in this life cycle. Furthermore, this webinar will discuss complaint handling implementation challenges, in addition to pitfall challenges. At the end of this course, there will be a conclusion section, where points to take into account with the integration of CAPA/change control/adverse event reporting/recalls/complaint files in the complaint handling life-cycle, will be detailed.

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. It will 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:

- Develop a satisfactory complaint procedure
- Explain how to document investigations
- Recognize when an event is reportable
- Implement an effective CAPA to address the complaint

course outline

Review of Learning Objectives
Module 1: What is a Complaint?

- Complaint Definition
- Medical Device and Drug Complaint Handling Requirements (US)
- Complaint sources

Module 2: How to Handle a Complaint

- Interrelationship of Complaint Handling, CAPA, Change Control, Adverse Event Reporting and Recalls
- Reportable events: when does a complaint become a reportable adverse event; what in itself is a reportable event; how does user error relate to adverse event reporting; voluntary and mandatory reports, and reporting timelines
- What may trigger a recall during the complaint investigation
- Recall Classifications

Module 3: How to Prevent Recurrence of a Complaint

- Complaint Handling Life-Cycle Process (including an example that embraces activities related to training in Module 2)
- Challenges
- Conclusion
- References

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.