COBBLESTONE

COURSE ID 3136

Effective Pharmaceutical Product Complaints Handling, Investigations & CAPA

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

- FDA's Expectations
- Regulatory Guidelines
- Steps in Complaint Investigation
- Robust CAPA (Corrective & Preventive Actions) & CAPA Tools

about the course

This 90-minute accredited training will equip attendees with an overview of the rules and regulations governing complaint handling and documentation within the pharmaceutical and related industries.

In compliance with 21 CFR Parts 210 and 211, manufacturers are required to maintain a complaint log or register, establish a complaint handling and CAPA (Corrective and Preventive Action) system, and implement SOPs (Standard Operating Procedures) for receiving, reviewing, and evaluating complaints. This process must involve key departments to ensure thoroughness.

While minimizing product complaints is a goal, an effective complaint handling procedure is essential for continuously improving the Quality System.

Live interaction with the instructor enables dynamic discussions and immediate clarifications. To verify attendance and encourage active interaction, those participating in the live training are required to have their webcams on during the course. The use of microphones and speakers or headsets is also strongly recommended.

who should attend

This course is beneficial for professionals in the pharmaceutical, biotechnology, and related industries, particularly those working in Quality Control, Supplier Quality Assurance, Quality and Compliance, Quality Assurance, and Regulatory Affairs.

It is especially valuable for CAPA investigators, manufacturing personnel, shipping and receiving staff, senior management, and auditors.

learning objectives

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

- Define the process and management of a complaint investigation as per 21 CFR Part 210 & 211.
- List various types of complaint classifications and benefits of filing a complaint.
- Explain the steps of Complaint Processing at a Manufacturing Unit.
- Analyze, approve, and take corrective actions based on the results of a complaint investigation.
- Evaluate the effectiveness of CAPA (Corrective & Preventive Actions).
- Summarize FDA's expectations as it applies to Complaint Handling.
- Review previous FDA-483 Observations and Warning Letter Citations Related to Complaints.
- Evaluate the content of a Complaint Handling and Investigation Standard Operating Procedure with an example of a complaint investigation report.

course outline

Review of Learning Objectives

Module 1:

- Regulatory Guidelines and Initial Consideration of a Complaint Process
- Understanding Complaints / Corrective actions / Preventive actions
- Benefits of Filing Complaints
- Classifications of Complaints

Module 2:

- Stepwise handling of Complaints Process for Investigations & CAPA
- Ensuring the effectiveness of CAPA
- Approving Product Complaint Investigation
- Feedback to Customers on CAPA
- Management responsibilities
- Documentation

Module 3:

- Understanding Risk-based approach to complaints handling
- Trending and FDA 483 / Warning letters
- Case Studies

Question and Answer Session

Assessment Opportunity

course instructor

Ranjit Barshikar, has over 40 years of Pharmaceutical / Biotechnology Industry experience in Quality, R&D, Manufacturing, and Regulatory Affairs. He is experienced in Quality Systems, Manufacturing Excellence, and the US and Foreign GMP Compliance. Being a QbD expert, he has trained more than 1500 Scientists from Global Multinational & Generic Companies, on Quality-by-Design (QbD) implementation & ANDA filings for QbD elements.

Ranjit has significant experience in Compliance and Quality Management, Validation, and GMP compliance auditing of manufacturing facilities for the production of sterile products by aseptic processing, solid dosage forms, etc. Additionally, he has extensive experience in ICH Q11-QbD implementation in API development, ICH Q14-Analytical Method Development by QbD & Validation, ICH Q12- Life Cycle Management. He has several articles published Globally on cGMP Compliances / QbD implementation. Ranjit is specialized in Process Analytical Technology (PAT) Process monitoring.

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.

The American Society for Quality (ASQ)-Recertification Opportunities

Cobblestone is committed to enhancing the ongoing professional development of Quality professionals and other stakeholders through appropriate learning activities and programs. Many Cobblestone courses offer training that may be helpful in obtaining required ASQ's recertification education units.

For more information, visit: www.asq.org