COBBLESTONE

COURSE ID 2861

Effective Complaint Handling Procedures

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- FDA's Expectations as it Applies to Complaint Handling
- Regulatory Guidelines and Initial Consideration of a Complaint Process
- Rules, Flow and Steps in Handling Complaint Investigation
- Processing, Approval, Corrective Actions, Trending and FDA Expectations for Complaint Handling Process

about the course

This accredited 90-minute training will provide attendees an understanding of the rules and regulations guiding complaint handling and complaint files within the life science industries. Per 21 CFR Part 820.198, "Each manufacturer shall maintain complaint files-establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit". While a product manufacturer hopes to keep complaints to a minimum, chances are that complaints will be received at some point. A good complaint handling procedure is critical, it creates an opportunity to assess what can be done to make improvements on the affected product where possible.

who should attend

This online training will benefit those involved in the manufacturing, processing, testing, and release of Pharmaceutical, Biotechnology, Drug, Biologics, Medical Device and In-vitro Diagnostics products amongst others. Personnel and management within the various manufacturing Industries, especially that personnel with tasks associated with:

• Quality Control	• Supplier Quality Assurance
• Quality and Compliance	• Quality Assurance
• Regulatory Affairs	• CAPA Investigators
• Manufacturing	• Shipping and Receiving
• Senior Management	• Complaint Handlers
• Auditors	

learning objectives

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

- Define, process, handle, evaluate, investigate, and manage a complaint investigation and files per 21 CFR Part 820.198
- List the various types of complaint classifications, and benefits of filing a complaint, and state the process flow of Complaint Processing at a Manufacturing Unit
- Process, analyze, approve, and take corrective actions based on the results of a complaint investigation.
- Summarize FDA's expectations as it applies to Complaint handling.
- Review previous FDA-483 Observations and Warning Letter Citations Related to Complaints.
- Establish 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

- Regulations Guiding Complaint and Complaint Files
- Details of Each Regulatory Parts Associated with a Complaint Files
- Definition of a Complaint
- Regulatory definition of a Complaint
- Reasons Why Customers Complain
- Positive Effect of Filing a Complaint
- Classifications of Complaints
    - Type A
    - Type B
    - Type C
- General Considerations of Complaint Handling

Module 2: Rules, Flow and Steps in Handling Complaint Investigation

- Rules of Complaints Handling for Organizations
- The Flow of Complaint Processing at a Manufacturing Unit
    - Detailed Flow of Complaint Handling and Investigation
- Steps in Handling of Complaints
    - Receiving Complaints
    - Receiving Complaints/Product Complaint Data Sheet
    - Technical Investigations
    - Laboratory Analysis Phase

Module 3: Processing, Approval, Corrective Actions, Trending and FDA Expectations for Complaint Handling Process

- Evaluating/Analyzing the results of a Complaint Investigation-Determining the Outcome
- Processing and Approving the Product Complaint Investigation
- Corrective Actions and Feedback to Customers
- Monthly Reports and Trend Analysis
- Detailed Product Complaint Report
- Documenting the Final Product Complaint Investigation Report
- Evaluation and Final Disposition of a Product Complaint Investigation
- Creating a Standard Operating Procedure for Complaint Processing
    - Details of a Complaint Handling SOP
- Example of a product complaint report Customer Complaint Record Book
- Effectiveness of a Complaint System
- Complaint Handling System in a Risk- Based Environment
- Feedback Loop and FDA-483 Observations and Warning Letter Citations Related to Complaints

Question and Answer Session

Assessment Opportunity

course instructor

Charity Ogunsanya has more than 31 years of extensive experience within the Biologics, Pharmaceuticals, Radiopharmaceuticals, Biotechnology, and Medical Device Industries and has been the Microbiology, Sterility Assurance, Contamination Control, Aseptic processing, Quality Control Subject Matter Expert (SME) for multiple fortune 100 companies.
She has a Bachelor of Science degree in Microbiology from the University of Benin-Nigeria and a Master's degree from the Advanced Academic Master's Biotechnology Program at Johns Hopkins University with a concentration in Biotechnology/Biodefense. She is the CEO/ Owner of her consulting firm named Pharmabiodevice Consulting LLC. Her consultancy provides support to Biologics, Pharmaceuticals, Radiopharmaceuticals, Biotechnology, and Medical Device Industries.

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