COBBLESTONE

COURSE ID 2764

# Effective Handling of cGMP Raw Materials

DIRECTED BY

**Charity Ogunsanya** — Owner/CEO of Pharmabiodevice LLC

90 MINUTE

ACCREDITED COURSE

**Course Topics Include:**

- Regulatory Requirements for all Incoming cGMP Controlled Materials
- Processing New Raw Materials Specification
- Routine and Yearly Confirmatory Testing for Suppliers and Manufacturers
- Disqualification of Test Parameters
- Issuing and Approving Raw Material Specification
- Processing Failed Raw Materials

## about the course

cGMP raw materials are the most critical ingredient of any product manufacturing step hence they must be controlled as stipulated in 21 CFR 110.80 Processes and Controls as well as applicable FDA regulations. Raw material control is an integral and essential process that ensures drug product quality, purity and potency. Drug product manufacturers must have a defined procedure that clearly shows how raw materials are received, stored, labeled, quarantined, tested, qualified, tracked, used, and discarded at the end of expiry.

This 90-minute accredited training will provide guidance to the process of ensuring that all the steps are followed to avoid producing an adulterated product as defined by the 21 CFR 110.80 Processes and Controls.

## who should attend

This online training is designed for personnel/companies in the Pharmaceutical, Biotechnology and Medical Device Industries. Employees and Management in the following areas will benefit greatly:

- QA and QC Analysts
- Raw Material Receipt and Testing
- Manufacturing Associates
- Quality Engineering Personnel

For information on pricing, terms/conditions, Team Training, and other courses, please visit **www.TrainwithCobblestone.com**

COBBLESTONE

| | |
|---|---|
| • Shipping, Receiving, Warehouse | • Supplier Quality and Auditors |

Personnel who manage these individuals would additionally benefit from this training by gaining a better understanding of the issues faced in ensuring a GMP-compliant raw material program.

## learning objectives

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

- Describe the appropriate ways to design the processing of all cGMP Controlled raw materials
- List the steps that every drug product manufacturer should follow in order to process all incoming cGMP controlled raw materials
- Develop defined procedures for receiving, storing, labeling, quarantining, testing, qualifying, tracking, and discarding controlled raw materials

## course outline

**Review of Learning Objectives**

**Module 1**

- Regulatory Requirements for all Incoming cGMP Controlled Raw Materials
- Receipt and Storage
- Processing New Raw Material Specification
- Procedure for Raw Material Initial Receipt
- Testing Requirements for all Incoming Materials

**Module 2**

- Test Requirements for Routine and Confirmatory Testing of Qualified Raw Materials
- Routine and Yearly Confirmatory Testing for Suppliers and
- Manufacturers
- Evaluation of Suppliers and Manufacturers after Approved Raw
- Material Specification Changes
- Disqualification of Test Parameters
- Requirements for the Comparison Criteria Used in the Confirmatory Yearly Testing

**Module 3**

- Confirmatory Testing Process
- Issuing and Approving Raw Material Specification
- Processing Failed Raw Materials
- Documentation
- Investigating OOS Associated with Rejected Raw Materials

**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