COBBLESTONE

COURSE ID 2765

REVISED!

Designing an Effective Environmental Monitoring Program

Determining a Cleanroom State of Control

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- Four Phases of Environmental Monitoring
- Sampling Plans
- Writing a Trend Report

about the course

The importance of designing an effective Environmental Monitoring (EM) program cannot be overemphasized. The data from this program provides an effective measuring tool that determines an effective cleanroom control from a Facility design, validation, implementation, disinfection, disinfectant effectiveness, gowning controls, cleanroom trafficking, aseptic controls, personnel training, and practices. It also serves as a critical program that supports and guides other contamination control key evaluators and other production and testing processes that help in ruling out cleanroom contamination using the data generated.

This 90-minute accredited training will discuss the various steps associated with the EM program from the Phases, through Validation, Implementation, Procedural Steps, Documentation Practices, Data Management, Trending of Data, EM Excursion, and the relationship of the cleanroom state of control and product impact and analysis per 21 CFR Parts 211.113 “Control of Microbiological Contamination” and 21 CFR Subpart G Section 820. 70..

who should attend

This 90-minute training will provide a great resource to product manufacturers with personnel in the Pharmaceutical, Biotechnology, Biologics, Drugs, Diagnostics, Cell Therapy, Medical Device, In-vitro Diagnostics industries within the following functions:

• QA/QC	• Microbiologist
• Chemist	• Analysts
• Validation	• Material Management
• Vendor/Suppliers	• Regulatory Affairs
• Facilities	• Manufacturing
• All Levels of Management	• Engineering

learning objectives

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

- Explain regulations guiding the environmental monitoring program
- List the four phases of the Environmental Monitoring (EM) program,
- Describe how to choose effective and compliant Environmental Monitoring sampling plans
- Process and relate the adequacy of an effective Environmental Monitoring excursion investigation to a continued cleanroom contamination and state of control.
- Evaluate and write an effective Environmental Monitoring trend report

course outline

Review of Learning Objectives
Module 1

- Regulations Guiding the Environmental Monitoring Program
- 4 Phases of the Environmental Monitoring (EM) Program:
- The Importance of an Environmental Monitoring Program and Cleanroom State of Control
- The Importance of an Environmental Monitoring Program and a Contamination Control Program
- Environmental Monitoring Program Test Media

Module 2

- Minimizing Cleanroom Contamination
- Environmental Monitoring Program Testing or Sampling Procedure
- Environmental Monitoring Sampling Plans
- Environmental Monitoring Sample Site Selection
- Alert and Action Levels

Module 3

- Training as a Key Criteria
- Types of Sampling
- Processing a Completed Environmental Monitoring Test Media
- Evaluation of Environmental Monitoring Excursion Trend Data
- Processing an Effective Environmental Monitoring Excursion Investigation
- Corrective and Preventative Action (CAPA)

Question and Answer Session
Assessment Opportunity

course instructor

Charity Ogunsanya has more than 30 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 has a Master's degree from the Advanced Academic Master's Biotechnology Program at the Johns Hopkins University with 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