COBBLESTONE

COURSE ID 2245

Introduction to Pharmaceutical Quality Management System

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- Benefits, Elements and Establishing a QMS
- Product Quality Review
- Quality Risk Management
- Contents of ICH Q10
- Continuous Improvement within the QMS

about the course

This 90-minute accredited online training course describes the requirements of an effective, comprehensively designed and correctly implemented Pharmaceutical Quality Systems (PQS) that incorporates Good Manufacturing Practice, Controls, Continuous improvements, and Quality Risk Management. All parts of the PQS should be adequately resourced with competent personnel, suitable and sufficient premises, equipment, facilities, processes, and effective procedures. This course is for employees that have been introduced to the basic cGMP concepts who need a deeper exposure to comprehensive Pharmaceutical Quality Systems requirements in the Pharmaceutical Industry per ICH Q10.

who should attend

This webinar will benefit various industries such as the Pharmaceutical, Biotechnology, Drug, Biologics, Medical Device and In-vitro Diagnostics Product Manufacturing Industries, especially those within various departments such as Quality Assurance Personnel and Management, Quality Control Personnel and Management, Laboratory Managers, Testing Analysts and Technicians, Manufacturing Personnel and Management, Supplier Quality Assurance Personnel and Management, Regulatory Affairs Personnel and Management, Shipping and Receiving Personnel and Management, Facility and Maintenance Personnel and Management, Microbiologist Personnel and Management, Engineering Personnel and Management, Materials Management Personnel and Management.

learning objectives

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

- Define the who, why and how of a Pharmaceutical Quality System (PQS)
- Describe the Benefits, elements, composition and how to implement an effective Quality Management Systems (QMS)
- Explain the requirements of Product Quality Review and Quality Risk Management
- Describe the five (5) segments and Contents of ICH Q10: Pharmaceutical Quality System
- Define Management responsibilities, Continual Improvement of Process Performance, Product Quality and Pharmaceutical Quality System

course outline

Review of Learning Objectives

Module 1

- What, how and why of a Pharmaceutical Quality System
- Benefits of a Quality Management Systems (QMS)
- Elements and Requirements of a Quality Management System (QMS)
- Establishing and Implementing Quality Management System (QMS)
- Steps to Implementing a Quality Management System
- Basic Requirements of cGMP
- Basic Requirements of Quality Control
- Product Quality Review
- Quality Risk Management

Module 2

- Contents of Pharmaceutical Quality Management System
- Relationship of ICH Q10 to Regional GMP Requirements, ISO Standards and ICH Q7
- Relationship of ICH Q10 to Regulatory Approaches
- ICH Q10 Objectives:
- Achieve Product Realization
- Establish and Maintain a State of Control
- Facilitate Continuous Improvement
- Enablers: Knowledge Management and Quality Risk Management
- QMS Design and Content Considerations
- Quality Manual
- Management Responsibilities
- Continual Improvement of Process Performance and Product Quality

Module 3

- Continual Improvement of Process Performance and Product Quality
- Lifecycle Stage Goals
- Pharmaceutical Development
- Technology Transfer
- Pharmaceutical Quality System Elements
- Continual Improvement of the Pharmaceutical Quality System
- Management Review of the Pharmaceutical Quality System
- Monitoring of Internal and External Factors Impacting the Pharmaceutical Quality System
- Outcomes of Management Review and Monitoring

- Basic Terms & Definitions related to Pharmaceutical Quality System

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