COBBLESTONE

COURSE ID 2244

REVISED!

cGMPs in a Nutshell

Current Good Manufacturing Practices

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- Regulations regarding 21 CFR Parts 210 and 211
- Fundamentals
- Benefits
- Key Parts
- Application

about the course

Most industries in the US are regulated by local, state, and federal regulators and pharmaceutical manufacturing companies are some of the most highly regulated, particularly at the federal level. Pharmaceutical Quality affects every American hence the FDA regulates the quality of pharmaceuticals very carefully. The main regulatory standard for ensuring pharmaceutical quality is the Current Good Manufacturing Practice (cGMPs) regulation for human pharmaceuticals.

While drugs represent only one third of the Food, Drug and Cosmetic Act, drugs are impacted by some of the most stringent FDA requirements known collectively as GMPs. Consumers expect that each batch of medicines they take will meet quality standards so that they will be safe and effective. Most people, however, are not aware of cGMPs, or how FDA assures that drug manufacturing processes meet these basic objectives. Recently, FDA has announced a number of regulatory actions taken against drug manufacturers based on the lack of cGMPs.

This 90-minute accredited training session discusses some facts that may be helpful in understanding how cGMPs per 21 CFR Part 210 and 211 establish the foundation for drug product quality and how it provides for systems that assure proper design, monitoring, and control of manufacturing processes and facilities.

who should attend

This online training will benefit professionals in the Pharmaceutical, Biotechnology, Drug, Biologics, Medical Device and In-vitro Diagnostics Industries

The training will be especially beneficial to personnel and management in the following areas and positions: QA/QC, Laboratory, Testing Analysts, Manufacturing, Suppliers, Vendors, Validation, Supplier QA, Regulatory Affairs, Shipping and Receiving, Facility and Maintenance, Microbiologists, Engineers and Materials Management.

learning objectives

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

- Describe the origin of the FDA and cGMP
- Describe the basic principles of cGMPs, enforcement authority and the need to comply
- Explain the "Fundamentals", "Benefits" and "Key Parts" of cGMPs
- Apply the detailed regulatory requirements guiding cGMP (21 CFR 211)
- Apply cGMP in the manufacture of quality products

course outline

Review of Learning Objectives

Module 1: The Regulations, Basics and Key Elements of cGMP

- Tragedies Preceding cGMP Regulations
- Origin of the Food Drug and Cosmetic Act
- The Regulations
    - Provisions/Interpretation of the Law (FDC Act)
    - Interpretations of the Law/Regulations
- Basics of cGMPs
- What is cGMP
- Inter-relationship between QA, GMP & QC
- What is the role of QA in CGMP
- Objectives of cGMP
- Importance/Benefits of cGMP
- cGMP Guidelines Applicable to Various Regulatory Bodies
- cGMP Guidelines and Links
- Fundamentals of cGMPs?
- Ten Principles of cGMP
- Key Parts of cGMP's - 21 CFR Part 211

Module 2: Various Key Parts of cGMP Requirements

- cGMP Categories
- Finished Pharmaceuticals
- Details of Subpart A: General Provisions
- Details of Subpart B: Organization and Personnel
- Details of Subpart C: Buildings and Facilities
- Details of Subpart D: Equipment
- Details of Subpart E: Control of Components and Drug Product Containers and Closures
- Details of Subpart F: Production and Process Controls
- Details of Subpart G: Packaging & Labeling Control
- Details of Subpart H: Holding & Distribution

Module 3: Detailed Description of the Key Parts of cGMP and Consequences of Non-Compliance

- Details of Subpart H: Holding & Distribution continues…
  - Warehouse
- Details of Subpart I: Laboratory Controls
  - Quality control department/laboratory
  - Documentation
  - 10 Attributes of a good document
- Details of Subpart J: Records & Reports
  - List of important documents in GMP/records and reports
- Details of Subpart K: Returned & Salvaged Drug Product
- Ten cGMP Thumb Rules
- The Inspection for Compliance with GMP Regulations
- Controlled Substances for Safeguards
- Consequences of Non-compliance to cGMP
- Legal consequences
- Business consequences

Question and Answer Session

Assessment Opportunity

course instructor

Charity Ogunsanya, (Owner/CEO), Pharmabiodevice Consulting LLC
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 Masters 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