COBBLESTONE

COURSE ID 2615

REVISED!

cGMP for Personal Care, Cosmetic and OTC Products

DIRECTED BY

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12 Hour

ACCREDITED COURSE

- cGMP Requirements for the United States
- ISO 22716 Requirements
- Quality Systems Approach to Compliance
- Quality Systems Manual Requirements
- Regulatory Enforcement
- Audit and Compliance Activities
- MoCRA Compliance

about the course

The importance of adhering to Current Good Manufacturing Practices (GMPs) cannot be overstated, especially as public trust in drug manufacturers is being challenged. GMP compliance is not only a regulatory requirement, but a business necessity.

To assist professionals in understanding and implementing GMP regulations, we offer an intensive 12-hour course on Current Good Manufacturing Practices for personal care, cosmetics, and OTC products. This course provides an in-depth overview of GMP regulations, including the Quality Systems approach, which can support regulatory compliance not only in the United States but also in the European Union. The course is designed to help formulators, production personnel, quality control and assurance teams, and management gain a thorough understanding of GMP regulations and their impact on all facets of a product's life.

The course covers each section of the Quality Systems Manual, providing insights into the processes that affect the writing, issuance, and maintenance of Standard Operating Procedures (SOPs). Participants will also learn about GMP requirements for facilities, personnel training, equipment qualification activities, process validation, component and product specifications, packaging and labeling controls, laboratory activities, warehousing, and shipping monitoring, the importance of process water system validation and care, complaints and recalls, and handling FDA inspections.

By taking this course, participants will gain a comprehensive understanding of GMP regulations and how they apply to their day-to-day operations. They will also develop how to implement and maintain effective quality systems to ensure compliance with regulatory requirements and improve their company's overall performance.

Since this training is highly interactive, those attending the live training event must have a webcam on their computer equipped with a microphone and speakers/headset to fully participate.

who should attend

This course is intended for all those involved in the development and manufacture of cosmetics, OTC drugs, and personal care products especially:

- Production Personnel
- Quality Assurance Personnel
- Research and Product Development Personnel
- Quality Control Personnel
- Quality Systems Auditors

learning objectives

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

- Explain the origin and importance of cGMP regulations
- Write, issue and maintain SOPs
- Describe the basics of Quality Systems Management
- List quality, general cGMP and personnel training requirements
- Explain the basics of:
  - Document preparation and retention needs
  - Production and process controls
  - Auditing for compliance
  - Complaints, recalls, and responsibilities
  - FDA inspections

course outline

Review of Learning Objectives

Session 1

- Introduction/Learning Objectives/History of GMPs
- Overview and Design of Quality Systems
- Components of Quality Systems
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- Components of Quality Systems

Session 2

- Building and Facilities
- Selection and Qualification of Equipment
- Calibration
- Equipment Cleaning and Sanitization
- Personnel and Training
- Purchase and Control of Raw Materials and Components
- Production and Process Controls

Session 3

- Laboratory Controls
- General cGMP Provisions
- Stability Testing and Requirements
- Records and Reports
- Complaint and Product Recall Management
- Labels and Labeling
- Product Holding and Distribution

Session 4

- Product Development and GMPs
- Documentation and Record Keeping
- Standard Operating Procedures (SOPs)
- Process Water Systems
- Validation Activities
- Auditing for Compliance
- FDA Facility Inspections
- Additional Regulatory Considerations
- MoCRA Compliance
- Case Studies

Question and Answer Session

Assessment Opportunity

course instructor

Karl Popp founded KPopp Consulting, LLC in 2010 as a consulting firm providing services to pharmaceutical, cosmetic and allied industries. He also is a practicing retail pharmacist. During his career he has been responsible for the development of products that have generated over $2 billion in sales.
From 1989 to 2008 he was associated with Stiefel Laboratories as Director of Product Development, and later as Senior Director of Special Projects coordinating external manufacturing, global research activities, and managing the corporation's intellectual property estate.

Prior to joining Stiefel, he was a Scientist and Project Manager for the Sterling-Winthrop Research Group. He earned his B. S. in Pharmacy from the Albany College of Pharmacy, an M.B.A. from Rensselaer Polytechnic Institute and is licensed to practice pharmacy in NY.
He has been active in the Society of Cosmetic Chemists in coordinating local educational seminars and is a past chair of the New England Chapter. He served on the National Committee on Scientific Affairs (1994-96), as Vice President-elect (1997), Vice President (1998), and as the Society's President in 1999. Mr. Popp was elected a Fellow of the Society in 2002 and granted Emeritus status in 2015. He is an inventor, an author and a scientist.
Karl Popp has lectured around the globe on new product development activities, GMPs and process validation, product life cycle management, and management of intellectual property. He has also served as an expert witness in matters before the U.S. federal courts.

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 12 contact hours, or 1.2 CEUs. For further information, visit www.iacet.org