

GMP in a Nutshell

DIRECTED BY

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ACCREDITED
COURSE

- cGMP goals
- Role of risk management
- Historical events
- Structure of the cGMP regulations
- Seven Essentials of GMPs
- Consequences of non-compliance
- What the cGMPs mean to the patients

about the course

The quality of pharmaceutical products is subject to rigorous scrutiny and meticulous control because anything less than the best possible quality could result in regulatory issues. More importantly, compromised quality could jeopardize patient safety, leading to potentially serious health risks. Current Good Manufacturing Practices (cGMPs) are regulations (21CFR210-211) used to ensure consistency in the manufacture of quality healthcare products. These regulations involve various departments in the manufacturing process.

As consumers of pharmaceutical products, whether they are prescriptions (“RX”) or over-the-counter (“OTCs”), we expect them to be safe, pure, and effective. It is up to those manufacturing and testing these products to ensure that current good manufacturing practices (cGMPs) are followed from the acquisition of raw materials to the distribution of the final dosage forms. Health authorities like the US Food and Drug Administration (FDA) periodically conduct inspections of facilities to ensure that the cGMP regulations are implemented and followed.

In this 90-Minute accredited training, participants will be provided an overview to GMPs for pharmaceuticals and the current U.S. FDA regulations. Seven Essentials of GMPs and examples of compliance versus non-compliance will be covered as well as the consequences for non-compliance.

Live interaction with the instructor enables dynamic discussions and immediate clarifications. To verify attendance and encourage active interaction, those participating in the live training are

required to have their webcams on during the course. The use of microphones and speakers or headsets is also strongly recommended.

who should attend

This course is designed for quality professionals, production and manufacturing technicians, packaging, distribution, and labeling staff, validation staff and any other sponsor organization representative that contract to GMP vendors and needs to understand the regulations.

This course is also for any others looking to enter the GMP sector or within the following industries:

- Pharmaceutical Science
- Research & Development
- Biologics
- Veterinary Drug Products

learning objectives

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

- Define key words and concepts related to current good manufacturing practice (cGMPs).
- Identify key events that contributed to the cGMPs.
- Describe how the regulations, guidelines, best of industry practice, and other factors contribute to “Current GMP Expectations”.
- Define the characteristics of a cGMP-compliant product.
- Discuss how quality system elements apply to your role and responsibilities.
- Identify the range of actions that can happen in the case of non-compliance with cGMPs.
- Identify the Seven Essentials of GMPs and discuss current GMP expectations that are relevant to your role and responsibilities.

course outline

Review of Learning Objectives

Where did the GMPs come from? Why do they exist?

- Focusing on the patient
- A quick look at 21 CFR 210 and 211
- SISPQ-A: Characteristics of a GMP-compliant product

What makes for “current” good practice?

- “Feasible / valuable,” guidelines

Seven Essentials of GMP

- Protect the product from contamination
- Prevent mix-ups
- Know what to do – and why – before doing it
- Document what really occurred (including data integrity)
- Strive for consistency and control
- Have management support and independent group that makes the final decisions
- Monitor, solve problems, and continually improve

Examples of non-compliance

Summary

Question and Answer Session

What are you taking back with you? What will you do differently? Assessment Opportunity

course instructor

James Vesper, PhD, MPH, Director of Learning Solutions at ValSource, has worked in the pharma industry for more than 40 years, first at Eli Lilly and Company where his last assignment was starting and leading the global GMP Training group. Before joining ValSource in 2017, he was president of LearningPlus, a training consultancy. His areas of interest are learning, human performance, root cause investigations, quality systems, risk management and knowledge management.

Dr. Vesper has worked globally as an invited speaker at international conferences and providing training and consulting services. He has authored multiple books and book chapters and conducted training for the PDA Training and Research Institute (TRI), WHO, US FDA, Ireland's HPRA, and PIC/S QRM Expert Circle.

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

Regulatory Affairs Professional Society (RAPS)

Cobblestone is committed to enhancing the ongoing professional development of regulatory affairs professionals and other stakeholders through appropriate regulatory affairs learning activities and programs. Cobblestone has agreed to follow RAPS- established operational and educational criteria. This course may be eligible for up to 12 credits towards a participant's RAC recertification upon full completion. The requirements and standards for recertification are developed and administered by the Regulatory Affairs Certification Board (RACB), which manages all areas of the RAC program. Additional information about RAC is available on the RAPS website at RAPS.org/rac.

