COBBLESTONE

COURSE ID 3036

Equipment Qualification in the GxP Environment

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

- Regulatory Considerations
- Human Consumption Considerations
- Historical Perspective
- Automated Equipment

about the course

Whether your operation is covered by GMP, GLP, or GCP, there is a regulatory requirement to ensure that all equipment used has been properly demonstrated and documented to be functioning properly. Commonly referred to as Installation Qualification, Operational Qualification, and Performance Qualification, IQ/OQ/PQ provides the framework under which this process can be appropriately performed. Overlooking this critical first step or improperly performing it can invalidate any data generated.

The course will explore the regulatory requirements associated with GxP environments. Adherence to GxP (i.e., documentation, laboratory, manufacturing, clinical), are precursor to medical/pharmaceutical production because it is codified (21CFR).

The 90-minute accredited training will delve into the controls and the laws needed to support GxP in Equipment Qualification. In addition, discussions will include the current understanding of the use of Automated Equipment focusing on Good Automated Manufacturing Practices (GAMPs).

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

who should attend

This webinar has been designed for professionals in the Pharmaceutical, Medical Device, and Biopharmaceutical industries. It will especially benefit engineers and scientists engaged in any FDA-regulated areas. Those working in validation, engineering, and manufacturing will find the course very valuable. In addition, managers and supervisors in these departments will also find the course beneficial.

- Engineers
- Managers
- Manufacturing
- Supervisors

learning objectives

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

- Articulate the reasons for GXP for respective role
- Explain what makes good equipment/manufacturing controls
- Describe the repercussions associated with not adhering to GXP

course outline

Review of Learning Objectives
Module 1:
Considerations associated with manufacturing products for Human consumption

- Why should there be controls (ethical considerations)?
- Laws (domestic and international) support the need for controls (practical/legal considerations).
- Aspects of 21CFR that support GxP and Equipment Qualification
- Aspects of Equipment Qualification (i.e., IQ, OQ, PQ)

Module 2:
Controls and their incorporation in Qualification efforts

- Equipment Controls (Analog and Digital)
- Process Controls (In-Process Quality Control Testing and Final Product Testing)
- Incorporation of Controls' testing in Qualification efforts
- When protocol generation is not perfect (deviations)

Module 3:
Automated Equipment

- Good Automated Manufacturing Practice (GAMP5)
- The V-Model
- Understanding your manufacturing needs
- Considerations for electro-mechanical equipment

Question and Answer Session

Assessment Opportunity

course instructor

Joy McElroy, has 10 years of experience as a consultant, and over 20 years total experience in the pharmaceutical and biotech industries, Ms. McElroy has gained extensive knowledge of Quality Assurance, Process and Cleaning Validation, and Equipment Qualification. She has written and executed Equipment Qualification and Validation Protocols for numerous Companies. Ms. McElroy specializes in Equipment Qualification, Sterilization, Cleaning Validation, and GMP Compliance Auditing. In 2019 Ms McElroy started her own company, McElroy Training and Consultancy. She currently works with Easi.

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