COBBLESTONE

COURSE ID 2929

IQ, OQ, PQ for the Laboratory

GMP Laboratory Control Professional Certification Program

DIRECTED BY

Charlie Neal, Jr. — Owner and Senior Consultant for Premier Quality Consulting

90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- Historical Overview: Birth of FDA, FDA Guidelines and Requirements
- Contents of Laboratory Qualification Protocols
- Vendor Qualification Packages and How They Impact the Qualification Effort
- Why Laboratory Equipment and Instruments Require Qualification
- Concluding Qualification: The Close-out Process

about the course

The FDA's 21 CFR Part 211.160 establishes the legal requirement for calibrating laboratory equipment. Now more commonly referred to as Installation Qualification/Operational Qualification/Performance Qualification (IQ/OQ/PQ), the qualification of equipment in a GMP Laboratory in the Pharmaceutical and Bio Pharmaceutical manufacturing operations are essential parts of the overall validation process and ongoing commercial batch release. Data generated in a GMP Laboratory cannot be considered valid if the acceptable performance of the instruments and equipment has not first been demonstrated.

This 90-minute accredited training course will discuss the differences between the IQ, OQ and PQ for laboratory instruments and how these qualification tasks differ. This training will also address their importance in demonstrating that laboratory instruments and equipment are fit for use.

This training is one part of the 10-course series required for the GMP Laboratory Control Professional Certification Program.

Attend this as a step in the certification process or as a stand-alone course for personal career advancement and training.

who should attend

This course is intended for professionals such as Engineers, Technicians, Department Heads, Teachers, Scientists, Validation Engineers and Consultants working in Academia, the Pharmaceutical Industry, Analytical Laboratories, and Contract Laboratories.

Those involved in Quality Control/Quality Assurance, Tech Services, Validation, and Process Development will benefit greatly from this training. Managers and supervisors of these individuals will benefit by understanding the challenges sometimes faced in their departments.

learning objectives

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

- Explain the origins of IQ, OQ and PQ
- Describe why laboratory equipment/instrument qualifications are necessary
- Discuss Laboratory equipment/instrument types
- Explain the role of Vendor Qualification protocols
- Prepare IQ, OQ and PQ protocols for laboratory equipment
- Explain how to conclude the Qualification Process

course outline

Review of Learning Objectives

Module 1: The Basis for the Requirement to Qualify Instruments and Equipment

- Historical Overview: Birth of FDA
- FDA Guidelines and Requirements

Module 2: How Instruments and Equipment Should be Qualified

- Why Laboratory Equipment and Instruments Require Qualification
- Contents of Laboratory Qualification Protocols

Module 3: How the Use of Outside Resources Can Benefit the Qualification Process

- Vendor Qualification Packages and how They Impact the Qualification Effort
- Concluding Qualifications

Question and Answer Session

Assessment Opportunity

course instructor

Charlie Neal, Jr., Owner and Senior Consultant for Premier Quality Consulting, has been in the Pharmaceutical industry for over thirty-five years. He has a wealth of hands-on technical experience acquired from the chemical, drug, device, and pharmaceutical industries. He has experience in Research, Development, Process Engineering, Validation, Technical Transfers, Manufacturing, Quality, Compliance, Project Management and Sales and Marketing. He has written and presented numerous papers on Qualification and Validation and their requirements.

He is a former member of the Institute of Validation Technology's Editorial Board. He has written and published articles on Technology Transfers and presented a paper on this topic in Tokyo, Japan. He has authored a chapter on Transdermal Process Validation that was published in the 3rd edition of "Pharmaceutical Process Validation". He has established and currently runs his own company, Premier Quality Consulting, which offers consulting expertise to the Pharmaceutical and Bio-Tech companies.

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.