COBBLESTONE

COURSE ID 1808

IQ/OQ/PQ

Executing Installation, Operational and Performance Qualifications in Support of Process Validations

DIRECTED BY

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

12 Hours

ACCREDITED COURSE

- Brief Regulatory History for Conducting Qualifications
- Differences between Qualification and Validation
- Quality Systems that Support Qualification
- Understanding Commissioning
- ICH Q9/ASTM Qualification Standards
- The Role of Risk Assessments
- The Role of Impact Assessments
- The Role of the Validation Master Plan
- Protocol Generation
- Acceptance Criteria
- Dealing with Issues during Qualification

about the course

The Installation/Operational/Performance Qualification of equipment, systems and facilities for sterile, oral solid dosage forms, liquids, finished and bulk drugs in the Pharmaceutical and Bio Pharmaceutical manufacturing operations are essential parts of the overall validation process. Equipment and systems must be installed, operated, and maintained within design specifications and facilities must be accepted as fit for use. Lastly, processes must be shown to be reliable and robust to assure the consistent quality and integrity of the final product.

This 12-hour accredited training provides a basic and thorough understanding of preparing, executing, reviewing, and approving qualification protocols. A Risk Based approach to impact critically assessment is also provided along with an overview of ICH Q9 Quality Risk Management and ASTM E 2500 approaches now being applied by the industry.

Though no library of completed protocols will be provided, examples and workshops will be utilized to enhance learning.

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

who should attend

This introductory/intermediate course is designed for individuals who need a basic, but thorough understanding of the Installation/Operational/Performance Qualification Process for equipment and systems in support of Process Validation for the manufacture of regulated products. The course will benefit individuals in:

- Engineering
- Technical Services/Validation
- Quality Control/Assurance
- University and Allied Health Care Professionals
- R&D
- Regulatory Affairs
- Production

Managers and supervisors of the above-listed individuals would also benefit from this training by becoming acquainted with the challenges and timelines for proper qualification.

learning objectives

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

- Define Validation Master Plans
- Describe the Impact/Risk Assessment
- Explain ICH Q9 and the Risk Based Approach
- Describe the ASTM Standard for Verification
- Restate the Integrated Commissioning Approach
- Prepare IQ/OQ/PQ Protocols
- Execute protocols
- Write Protocol Summary Reports
- Describe the Quality Systems necessary to support validation

course outline

Review of Learning Objectives/Validation Overview

- History
- Regulatory Guidelines
- Common Definitions
- "V" Model
- Validation vs Qualification

Validation Master Plan

- The Role of the Master Plan
- Typical Master Plan Content

Development of Qualification Protocols

- Sections (Minimum Requirements)
- Protocol Format
- Responsibilities
- Equipment/Systems to be Qualified
- General Requirements for Execution

Supporting Quality Systems

- Calibration Program
- Maintenance
- Preventive Maintenance Programs/Logs/Equipment Files
- Training
- Documentation Management
- Change Control

Alternate Approaches to Qualification

- Risk-Based Commissioning/Qualification
- Integrated Commissioning & Validation
- ASTM E2500
- Impact Analysis Workshop

Qualifications: Installation Qualifications

- IQ Protocol Structure
- IQ Protocol Acceptance Criteria
- IQ Protocol Examples
- Preparing the IQ Summary Report

Operational Qualifications

- OQ Protocol Structure
- OQ Protocol Acceptance Criteria
- OQ Protocol Examples
- Preparing the OQ Summary Report

Performance Qualifications

- PQ Protocol Structure
- PQ Protocol Acceptance Criteria
- PQ Protocol Examples
- Preparing the PQ Summary Report

Common Issues

- Deviations and Reporting
- Deviation Types
- Deviation Corrections
- Deviation Investigation System

Concluding Qualification

- Summary Approvals
- Document Repository
- What's Next?

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. His experience crosses into many areas of these industries including Research, Development, Process Engineering, Validation, Technical Transfers, Manufacturing, Quality, Compliance, Project Management and Sales and Marketing.

Mr. Neal has written and presented numerous papers on Qualification and Validation and their requirements in the Life Science industry. His expertise was further expanded while an active member of the Institute of Validation Technology's Editorial Board. Mr. Neal has written and published articles on Technology Transfers and has presented on these topics internationally, including in Tokyo, Japan. He has authored a chapter on Transdermal Process Validation that was published in the 3rd edition of "Pharmaceutical Process Validation".

His company, Premier Quality Consulting was, established to offer 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 12 contact hours, or 12 CEUs. For further information, visit www.iacet.org