VAL03 Commissioning and Installation Qualification

Approximate study time: 1.5 hours

Level: Introductory/Intermediate

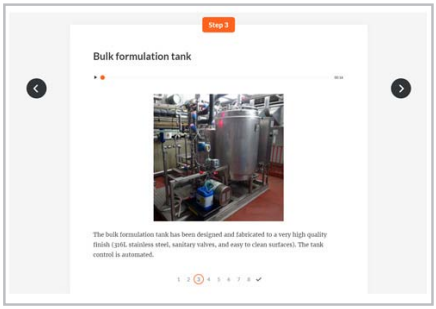
Audience: Manufacturing personnel

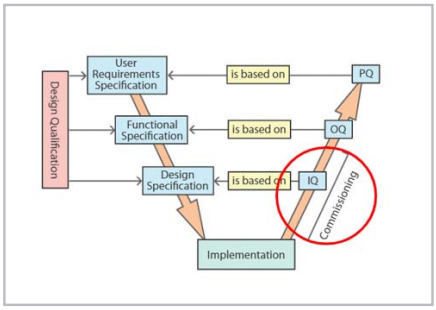
Category: Validation, GMP

Region: North America, Europe, other

CPD Points: 1.5

Module outline
- Introduction
- Basics of commissioning and Installation Qualification
- Impact assessment
- Installation Qualification
- IQ documentation
- Assessment





Before equipment can be used routinely in production, it must first be commissioned and, if necessary, undergo Installation Qualification (IQ). This module describes commissioning and IQ requirements and procedures in the medicines and healthcare products industries. It follows the activities of a typical validation team as they carry out a project for a pharmaceutical company.

Who will benefit from this module?

Manufacturing personnel in the pharma/bio-tech, dietary supplement, and medical devices industries need to understand the principles and practice of validation, as set out in this module. In particular, the module provides essential learning for engineering, production, and quality management personnel in the pharmaceutical industry.

Learning objectives

- Define commissioning and Installation Qualification activities and scope
- Explain the purposes of, and differences between, commissioning and qualification
- Determine qualification requirements based on an impact assessment
- Prepare and execute IQ protocols
- Describe requirements for the content and approval of IQ reports

Module outline

Introduction
A brief introduction to the validation project that provides a case study for Zenosis modules on validation.

Basics of commissioning and Installation Qualification
This session defines commissioning and Installation Qualification (IQ), summarises their purposes, and identifies differences between them. It outlines the progression of commissioning and IQ in a validation project, along with the roles of Factory Acceptance Testing and Site Acceptance Testing. It describes how responsibilities for commissioning and IQ are assigned in a typical company. It identifies vendor equipment documentation that may be included in specifications, as well as the contents of commissioning reports.

Impact assessment
This session explains the roles of impact assessment and criticality assessment. It discusses how to draw system boundaries and use impact assessment to determine the scope of qualification work required.

Installation Qualification
This session describes how to decide which components of each system require qualification and which need only be commissioned. It identifies systems/services that support the production line, and gives examples of tests applied to them as part of qualification. It identifies important parts of IQ protocols, and gives examples of qualification criteria specified in protocol test sheets. Finally, it outlines requirements for calibration of devices, instruments and systems.

IQ documentation
This session specifies important characteristics of IQ protocols, and outlines how to execute the protocols. It identifies documents that typically need to be completed during qualification. It specifies contents of an IQ report, and identifies requirements for the sign-off of protocols and reports.

Assessment
The assessment tests the learner's assimilation of the module's content.