# VAL04 Operational and Performance Qualification

**Approximate study time:** 1 hour

**Level:** Introductory/Intermediate

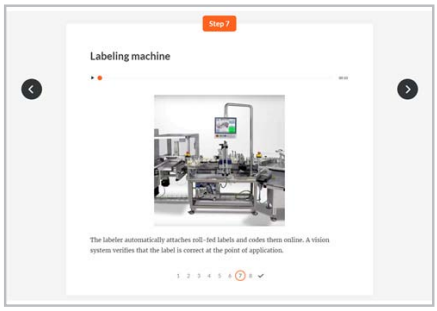
**Audience:** Manufacturing personnel

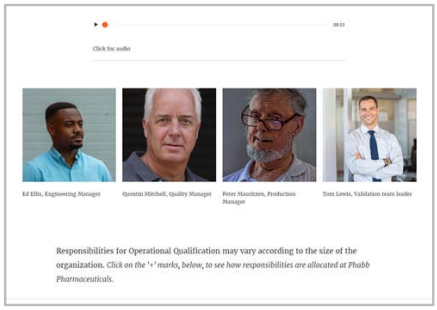
**Category:** Validation, GMP

**Region:** North America, Europe, other

**CPD Points:** 1

**Module outline**
- Introduction
- Operational Qualification
- Performance Qualification
- Assessment




Having undergone Installation Qualification, before equipment can be used routinely in production, it needs to undergo Operational Qualification (OQ) and Performance Qualification (PQ). This module describes OQ and PQ 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/biotech, 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 OQ and PQ
- Explain the scope of OQ and PQ
- Identify typical responsibilities of company staff for OQ and PQ
- Specify the steps of OQ and PQ and describe activities to be carried out
- Prepare, approve and execute OQ and PQ protocols
- Write OQ and PQ reports

## Module outline

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

**Operational Qualification**
This session explains how to identify equipment, systems and services to which Operational Qualification (OQ) applies. It identifies typical responsibilities of company staff and vendors for OQ. It specifies prerequisites for OQ and describes steps in the OQ process. It identifies tests required of equipment, systems and services during OQ. The learner is shown how to develop, review and execute protocols that specify the tests required, and to write OQ reports.

**Performance Qualification**
This session specifies the purpose of Performance Qualification (PQ), and identifies typical responsibilities of company staff for PQ. It specifies the steps of PQ and describes the activities to be carried out, including environmental microbial monitoring where necessary. The learner is shown how to prepare, review and execute PQ protocols and write PQ reports.

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