VAL07 Computer Systems Validation, Part 2: Implementation

Approximate study time: 1 hour

Level: Introductory/Intermediate

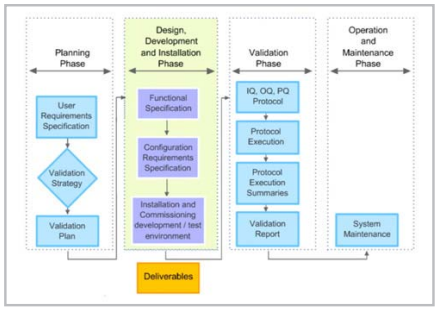
Audience: Manufacturing and ICT personnel

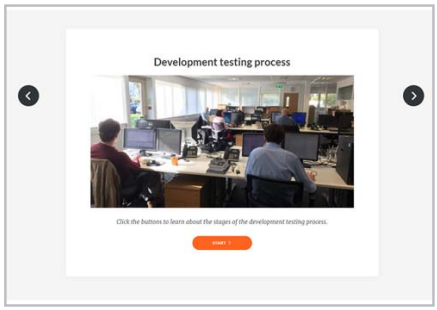
Category: Validation, GMP, ICT

Region: North America, Europe, other

CPD Points: 1

Module outline
- Design, development and installation phase
- Validation phase
- Operation and maintenance phase
- Assessment





This module describes the design, development and installation phase, the validation phase, and the operation and maintenance phase of the validation of computerised systems in medicines and healthcare products manufacturing environments. It continues to follow the progress of a pharmaceutical company's project to validate a new dispensary control system.

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 computer systems validation, as set out in this module. In particular, the module provides essential learning for engineering, information and communication technology, production, and quality management personnel in the pharmaceutical industry.

Learning objectives

- Describe the design, development and installation phase of projects to validate computerised systems
- Describe the validation phase of such projects
- Describe the operation and maintenance phase
- Determine which systems to validate
- Determine the amount of validation required, and the strategy to use

Module outline

Design, development and installation phase
This session specifies the roles of functional and design specifications. It outlines the development testing process, and describes the formulation and use of test plans, cases and scripts. It identifies characteristics of good testing practices, and emphasises the importance of development change management.

Validation phase
This session specifies the activities to be performed in the validation phase, and outlines their timing. It states the purposes of platform qualification, application installation qualification, operational qualification, and performance qualification. It specifies tests typically carried out in operational qualification and performance qualification. Finally, it describes the roles of validation change management and the validation report.

Operation and maintenance phase
This session describes the measures that need to be in place during the operation and maintenance phase. It outlines the management of the decommissioning of a system. It identifies changes that need to be controlled in the operation and maintenance phase.

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