VAL06 Computer Systems Validation, Part 1: Planning

Approximate module time: 1 hour

Level: Introductory/Intermediate

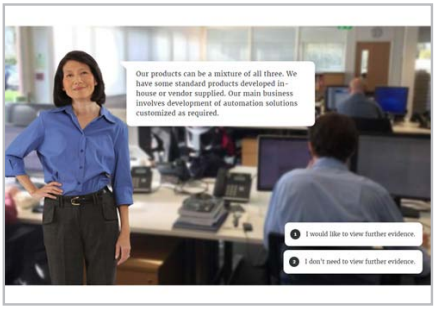
Audience: Manufacturing and ICT personnel

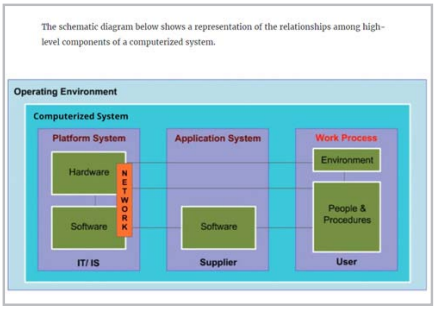
Category: Validation, GMP, ICT

Region: North America, Europe, other

CPD Points: 1

Module outline
- Introduction
- The planning phase
- Validation strategy and plan
- Assessment





In the medicines and healthcare products industries, computerised systems used in automated manufacturing or laboratory processes to which Good Manufacturing Practice requirements apply need to be validated. This module describes the planning of such validation. It follows the work of a pharmaceutical company's team as they validate the dispensary control system for a new production line.

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 computerised system 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

- Define computer systems validation
- Outline criteria for selecting systems to be validated and for initial estimation of the degree of validation required
- Access important guidance documents by industry bodies and regulatory authorities
- Identify the phases of the computer systems lifecycle and describe the activities that are performed in each phase
- Describe considerations influencing validation strategy
- Assess software suppliers and their products
- Outline the contents of a validation plan

Module outline

Introduction
This session defines computer system validation and specifies its benefits. It identifies, in general terms, which systems need to be validated. It identifies sources of guidance from industry bodies and regulatory authorities, and it discusses the importance of protection of data integrity.

The planning phase
This session identifies the phases of the computer systems lifecycle, and outlines the activities that are performed in the planning phase. It specifies the purposes of a User Requirements Specification and a traceability matrix.

Validation strategy and plan
This session specifies criteria for regulatory assessment. It outlines FDA requirements on electronic records and electronic signatures. It describes in detail how to assess software suppliers and their products. It sets out principles of risk management. Finally, it outlines the contents of a validation plan, including change management.

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