

Validation of Computerized Systems in the Pharmaceutical Industry

Q22040

2 days



Course Overview

This course will introduce attendees to the following areas of software validation in the Pharmaceutical industry:

- Terms, Definitions, and legal regulations in EU and USA pharmaceutical industries
- Regulatory requirements for GxP compliant computer systems
- Major parts of a QM system necessary for computer validation according to GxP
- Planning and execution of computer system validation
- Creation of most important SOPs necessary for validation of computerized systems
- Auditability and typical examples of audit findings and warning letters

Course Objectives

By the end of this course, attendees will discuss and understand:

- Basic understanding of what's required in this industry
- What is expected from the regulatory authorities
- Why is Validation important - it's about patient safety and healthiness
- How is Validation conducted and how can it be assured that Systems remain validated over time
- What can happen, if "you're not in compliance"

Who should attend?

Members of staff in pharmaceutical industry and their suppliers. QA personnel and IT personnel who are involved in the computer validation will get a good knowledge of the GxP fundamentals.

Prerequisites

None

Related Certifications

None

Recommended Follow-on Courses

None

