



Online Course 12 C „From Functional Testing to Handover“

Belonging:	GMP for Engineers
Learning Goal:	You will gain important knowledge about the individual phases of the qualification of a facility. This includes computer validation, how tests and documentation have to be designed and what has to be considered when handing over the equipment to the operator.
Target Audience:	Project managers, technicians and engineers responsible for planning, operation or for qualification, operators, quality assurance
Processing Time:	Approx. 45 min.
Personal Certificate:	After successfully completing the final test

Concept:

You will receive important information about the individual phases of the qualification of a system. This includes computer validation, how tests and documentation have to be designed and what has to be considered when handing over the system to the operator. With the help of the qualification it shall be shown that the equipment and facility used is suitable for the planned purpose. Qualification activities are therefore always associated with many tests and trials in the individual phases.

Content:

- 9 Chapters
- 2 Exercises
- 1 Summary
- 1 Final test

Learning Component 1: Introduction

- Welcoming address
- Everyday Example
- Overview of the course unit
- Qualification activities in the individual planning phases

Learning Component 2: Qualification Fundamentals

- Elements of qualification (IQ, OQ, PQ)
- Regulations
- Validation/qualification master plan (VMP/QMP)
- Risk analysis determines the scope of qualification
- Acceptance criteria

Learning Component 3: Documentation of the Qualification

- Contents of a Documentation
- The qualification report
- Variants of the four-eyes principle



Learning Component 4: Installation Qualification (IQ)

- Conformity of technical documentation and planning with reality
- Individual steps of installation qualification
- Typical Elements of an Installation Qualification

Learning Component 5: Operational Qualification (OQ)

- Conformity of the functionality with the requirements from the specification sheet
- Typical functional qualification tests
- Deviation lists and work instructions
- Initial calibration, test equipment, testing

Learning Component 6: Performance Qualification (PQ)

- Correct interaction of several systems
- Exercise
- Requirements for a performance qualification

Learning Component 7: Qualification of Computerised Systems

- Regulatory Basics
- Consideration of GMP-compliant processes
- The V-model
- Acceptance test/system test/integration test
- System environments
- Whitebox and blackbox testing

Learning Component 8: Handover to the Operations

- Procedure

Learning Component 9: Key Points at a Glance

- Exercise
- Summary of the course unit

Final Test

Technical Information:

You can easily access the e-learning tool GMP:READY - GMP for Engineers on the internet via user name/password.

Important: User name and password will be set up for the designated trainee. End-user has to be specified when placing the order!

The course is displayed on the internet via FIT² Coach.