

Qualification and Validation – from Requirements to Testing|company

Get the Basics of Qualification and Validation

Gain an understanding of the requirements for qualification and validation when new equipment or processes are introduced in pharmaceutical manufacturing – and learn how to ensure traceability from requirements to testing.

About the course

[Read about the benefits of a company course](#)

Before new facilities, equipment or processes are put into use in pharmaceutical manufacturing, it is important to demonstrate that they are fit for their intended purpose and deliver the expected results.

In this course, we cover the requirements for qualification and validation to help you understand the purpose of these activities.

You will learn what it means to demonstrate that facilities, equipment and processes are suitable for pharmaceutical manufacturing.

We cover the following topics:

- The difference between qualification and validation and the purpose of these activities.
- Relevant regulatory requirements.
- An overview of all phases of qualification and validation.
- The importance of maintaining a clear link from requirements to testing, using the V-model as a framework.
- Roles and responsibilities, including collaboration with suppliers.

The course combines presentations with practical group exercises.

Target group

The course is relevant for employees who are about to work with qualification and validation in pharmaceutical manufacturing.

Sign-up

Course

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Format

Half-day in-company course

Choose date and sign up

Hillerød 31. dec – 31. dec. 2040

This may include new validation specialists as well as testers, QA professionals or project managers who will be preparing, testing or reviewing qualification and validation documentation.

What you gain

Benefits for employees

- You understand the difference between qualification and validation and know when each is applied.
- You gain an overview of the phases of qualification and validation – from requirements specification to testing.
- You understand roles and responsibilities, including collaboration with suppliers.

Benefits for the organisation

- Employees understand the purpose of qualification and validation and can thereby contribute to robust processes.
- Employees can create a stronger link from requirements to testing, thereby strengthening the quality of documentation.
- Employees contribute to more effective collaboration with suppliers.

Course program

During this course, we cover the following topics:

- Purpose of qualification and validation
- Regulatory requirements
- The V-model and activity flow
- Maintaining a clear link throughout the documentation
- Roles and responsibilities

The course combines presentations with group exercises.