

# Introduction to the Manufacture of Sterile Medicinal Products for Operators|company

## Get New Operators Ready to Work in Your Sterile Manufacturing Environment

The course prepares new operators to work in accordance with GMP requirements in your organisation and gives them a clear understanding of the requirements that apply to sterile manufacturing.

At the same time, they are introduced to the mindset required when working with the manufacture of sterile medicinal products in a GMP-regulated organisation.

## About the course

Read about the benefits of a company course

In just two days, new operators gain:

- A basic understanding of the applicable GMP requirements for the manufacture of sterile medicinal products.
- An understanding of how the requirements are applied in practice in a GMP-regulated organisation.
- A shared foundation for further training in sterile processes.

The course focuses on how GMP requirements help ensure that medicinal products consistently meet the required quality standards in your manufacturing environment.

Employees gain knowledge of key topics such as aseptic working techniques, personnel behaviour in sterile environments, and requirements for airlocks, facilities and layout.

The course also covers basic microbiology in relation to production hygiene, as well as an introduction to topics such as environmental monitoring, smoke studies and media fills in sterile manufacturing.

The training can be based on the company's own workflows and procedures, making it easier for employees to apply what they have learned in practice.

The course combines presentations, quizzes, games and practical exercises. The theory is supported by the instructor's practical experience from the life science industry, creating a strong connection between theory and practice in your organisation.

### Sign-up

#### Course

Introduction to the Manufacture of Sterile Medicinal Products for Operators|company

#### Format

2 days in-company course

### Choose date and sign up

Hillerød 31. dec – 31. dec. 2040

After the course, employees will have a basic understanding of the key aspects of sterile manufacturing and the behaviour expected in the production environment. They will therefore be better prepared for further training.

This provides a shared foundation for appropriate behaviour and compliance with GMP requirements in sterile manufacturing environments.

## Target group

The course is designed for operators who are new to GMP-regulated sterile manufacturing.

It is a prerequisite that participants have completed a GMP course prior to attending this course.

## What you gain

### Benefits for employees

- You understand the GMP requirements and the importance of complying with them in your work.
- You contribute to ensuring quality in your organisation.
- You understand why aseptic working techniques are important.

### Benefits for the organisation

- Employees have a good understanding of the manufacture of sterile medicinal products.
- Employees contribute to ensuring GMP compliance.
- Employees are ready for further training in the company's specific tasks.

## Course program

The course is a 2-day course.

Day 1: 09:00–16:00

- Introduction to sterile medicinal products and the legislation governing their manufacture
- Microbiology and personal hygiene

- Aseptic working techniques

Day 2: 09:00–16:00

- Smoke studies and media fills
- Environmental monitoring
- Cleaning and disinfection

The course combines presentations, quizzes, games and practical exercises.

The theory is supplemented by the instructor's own practical experience from the pharmaceutical industry.