

Basic GMP|company

Understand GMP and learn how your organisation works with GMP in practice

Get a solid introduction to GMP and the EU's regulations for pharmaceutical manufacturing and build a shared understanding across your team of the requirements, responsibilities, and mindset needed to operate in a GMP-regulated environment and produce safe, high-quality medicines.

About the course

Read about the benefits of a company course

GMP (Good Manufacturing Practice) is a set of rules and standards that ensures medicines are manufactured consistently and safely. GMP creates quality, traceability, and patient safety.

On the course, employees receive:

- a solid introduction to GMP and the EU's regulations for the manufacture of medicinal products
- a basic and shared understanding of requirements, responsibilities, and the mindset needed to work in a GMP-regulated environment
- a common understanding of their role in ensuring consistent compliance with GMP across the organisation.

In addition, employees are introduced to the life science industry and the journey of a medicinal product from development to market, gaining insight into the relationship between legal requirements, quality, and patient safety.

We take an in-depth look at the EU GMP rules (EudraLex Vol. 4) and work with key topics such as:

- The Pharmaceutical Quality System
- Risk Management
- Requirements for Production
- Personnel Responsibilities and Behaviour in GMP Settings
- Facilities and Equipment
- Documentation and Good Documentation Practice

The training alternates between presentations, discussions, exercises,

Sign-up

Course

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Format

2 days in-company course

Choose date and sign up

Hillerød 31. dec – 31. dec. 2040

and GMP simulations.

The training alternates between presentations, dialogue, exercises, and GMP games, providing both theoretical knowledge and practical understanding that can be applied in daily work.

Examples from the company's own day-to-day operations can be included, making the learning directly relevant to employees.

Employees gain insight into why GMP compliance is necessary to ensure patients have access to safe, high-quality medicines.

This gives employees a common foundation for working according to GMP principles in their daily tasks.

Target group

The course is aimed at academics and technicians who are inexperienced with GMP, as well as new employees in the life sciences industry who need a basic understanding of GMP.

It is also suitable for those already working with GMP who want a deeper understanding of the rationale behind their work and the GMP regulations.

What you gain

Benefits for employees

- You understand the fundamental principles of GMP and the structure of the EU GMP guidelines.
- You can work more confidently with documentation, quality and GMP requirements.
- You can apply a basic GMP mindset and contribute to ensuring the quality of medicines.

Benefits for the organisation

- Employees has an understanding of GMP, quality, GMP-mindset and responsibility.
- Employees works more consistently and correctly according to applicable regulations.
- Employees contributes to improved quality and patient safety.

Course program

The course is a two-day course.

Day 1: 09:00 – 16:00

- Introduction to the Life Sciences Industry
- The Path of a Medicinal Product to the Market
- Legal Framework and Structure of EudraLex Vol. 4
- Pharmaceutical Quality Systems and Risk Management
- Facilities and Equipment

Day 2: 09:00 – 16:00

- Production and Raw Materials
- Documentation and Good Documentation Practice
- Deviations and Changes
- Personnel, Behavior and Hygiene
- GMP Mindset in Practice
- Interactive GMP Game

The course consists of presentations, discussions and exercises.