

Basic GMP

Understand the impact of GMP in your work

You will get an insight into the GMP regulations. We will explore the requirements for the personnel, premises, and equipment as well as the many requirements to documentation. After the course, you will know what working according to GMP means and you understand the mindset it takes to produce safe medicinal products.

In just two days, you will get a basic knowledge of the basic EU-GMP regulations (EudraLex Vol. 4), and you will gain a foundation for understanding the GMP requirements in daily operations. After the course you will be able to participate in practical problem solving when it comes to interpretation of the GMP requirements in your work.

In this course we will explore topics such as quality, risk assessment and personnel behaviour. You will gain knowledge of what is required of premises and equipment to ensure the quality of medicinal products. You will also gain a thorough understanding of the expectations to GMP documentation.

You will be introduced to the GMP regulations through presentations and cases, where you will have the opportunity to discuss how the requirements should be interpreted in practice.

When you discuss the requirements with the other participants, you will gain a broader understanding of how the mindset of the personnel helps ensure compliance with GMP.

In this way, you will get both a theoretical and practical basis for understanding and complying with the GMP requirements.

The days are a mix of presentations, exercises, and group work. Various GMP issues are discussed based on cases and experience.

This course can also be conducted on-site at the company - [see here](#)

[You can find the course in Danish here.](#)

At the course you will meet:

Louise Schou Petersen, Educational Consultant, Pharmakon

Helle Bøg, Educational Consultant, Pharmakon

Course facts

FORMAT

2 days

RATING

4,77 out of 5

PRICE THIS YEAR

15.500 DKK excl. VAT,
overnight stay included

Sign-up dates

Hillerød

21. nov. — 22. nov.
2024

Do you have questions about this course?

Kontakt

Kursuskoordinator
Elizabeth Ruelykke
+45 48 20 62 64
erk@pharmakon.dk

Target group

The course is intended for those who have limited GMP knowledge and in need of an overview of the GMP regulations, this course is for you, no matter whether you are supporter, manager or other in a production department, QC or QA. The course is also relevant for those who already work in a GMP regulated facility and wants to gain insight into the regulations to better understand the implementation of the rules.

Your benefits

- you are familiar with the GMP regulations and know how to comply with them in your work
- you can contribute to quality assurance in your company
- you will be aware of how the mindset and attitude towards documentation helps ensure the quality of medicinal products.

Your company's benefits

- your employee understands the importance of compliance with GMP regulations
- your employee helps ensure compliance with GMP
- your employee contributes to interpretation of the GMP requirements.

Course agenda

The course is a two-day course. Accommodation is included.

Day 1: 09.30 – 21.00

- GMP Requirements
- Premises and equipment
- Risk assessment

Day 2: 09.00 – 16.00

- Production
- Documentation
- Personnel

The days will be a mix of presentations and group work.
Various GMP issues are discussed based on cases and experience.