Sterile 2 - Manufacturing of Sterile Batch

Learn how to work in compliance with Good Manufacturing Practice (GMP) regulations when producing a sterile batch. You must have completed Sterile 1 before enrolling in this course. You will gain the skills to independently manufacture a sterile batch in accordance with GMP regulations, including the correct handling of sterile raw materials, primary packaging, formulations, and dosage forms. Based on your knowledge of environmental monitoring planning and monitoring methods, you will be able to carry out environmental monitoring according to established procedures.

You will be able to operate and monitor industrial processes in sterile manufacturing in compliance with GMP regulations. You will also learn to optimise processes through self-inspection and contribute to identifying and solving production-related problems.

You will be able to apply correct working techniques and appropriate behaviour during cleaning and disinfection procedures.

Course Content

- Manufacturing sterile batches in accordance with GMP regulations.
- Handling raw materials, formulations, and dosage forms.
- Focus on environmental monitoring methods.
- Focus on GMP regulations in industrial manufacturing processes.
- Understanding your role in process optimisation and problem identification.
- Correct working techniques and appropriate behaviour during cleaning and disinfection.

Target Group
This course is primarily aimed at employees in the pharmaceutical industry and individuals seeking employment in the pharmaceutical sector.

Entry Requirements
You must have completed Sterile 1 – Manufacturing of Sterile Medicinal Products before enrolling in this course.

Certification
Upon successfully passing the examination on the final day of the course, you will receive an officially recognised AMU certificate of competence.

Kursuspris

Inden for AMUs målgruppe:
DKK 2.180,00

Uden for AMUs målgruppe:
DKK 9.731,50

Tilmelding

Kursusinfo



Three good reasons why to take this course

1. **Learn How to Manufacture Sterile Products Correctly:** This course provides you with the knowledge and practical skills needed to independently manufacture a sterile batch. You will learn how to handle raw materials, packaging, and products in compliance with relevant regulations, ensuring consistently high quality standards.
2. **Master Environmental Monitoring and Problem-Solving:** You will learn how to plan and carry out environmental monitoring in sterile manufacturing environments and use this knowledge to optimise production processes. You will also develop the skills to identify and solve problems that may arise during production.
3. **Work Efficiently in Compliance with Regulations and Procedures:** With a focus on appropriate behaviour, cleaning, and disinfection, you will acquire the techniques needed to ensure that all work is carried out in accordance with applicable requirements, regulations, and procedures.

Fag: Fremstilling af steril batch, Steril 2

Fagnummer: 21907	**Varighed** 10 dage
Inden for AMUs målgruppe: DKK 2.180,00	**Uden for AMUs målgruppe:** DKK 9.731,50

Målgruppe: Kurset er primært udviklet til ansatte i pharmaindustrien. Det forventes, at man har gennemført kurset 21906 Fremstilling af sterile lægemidler, Steril 1, eller har tilsvarende kompetencer.

Beskrivelse: Efter gennemført kursus har deltageren:
Viden om aseptik.
Viden om planlægning af miljømonitorering og anvendelse af monitoreringsmetoder.

Efter gennemført kursus kan deltageren:
Selvstændigt foretage korrekt håndtering af sterile råvarer, primær emballage, bulkprodukter, færdigvarer og mediefyld.
Foretage miljøkontrol efter udleverede forskrifter.
Foretage procesoptimering ved hjælp af selvinspektion og dermed medvirke til problemidentifikation samt problemløsning.
Anvende korrekt arbejdsteknik og adfærd under rengøring og desinfektion.