

Annex 1 – Aseptic Manufacturing|company

Understand the Requirements for Sterile Medicinal Products and Learn How to Apply Them in Your Organisation

Sterile medicinal products place extremely high demands on the environment, equipment, processes and behaviour.

This company-focused course gives employees an overview of Annex 1 and strengthens their ability to assess, document and prevent contamination in everyday practice.

About the course

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

We take a closer look at key topics within contamination control (CCS) in sterile manufacturing, including environmental monitoring, media fills, cleanroom classification, cleaning and disinfection, and personnel hygiene.

This gives employees a shared professional foundation for working with sterile processes and contamination control across the organisation.

We also look at the microorganisms typically found in manufacturing environments and how employee behaviour and working practices contribute to preventing microbial contamination.

Throughout the course, employees work with case studies that provide an opportunity to discuss how the requirements of Annex 1 should be interpreted and applied in real-life situations in day-to-day operations.

We are happy to incorporate examples from the company's own operations, ensuring that the training is relevant to employees' everyday work.

The course combines presentations and exercises and is particularly relevant for employees with a basic understanding of GMP who want to explore Annex 1 and sterile processes in greater depth.

When several employees participate together, the course creates a shared foundation for consistent compliance with requirements and for further improvement in practice.

Sign-up

Course

Annex 1 – Aseptic
Manufacturing|company

Format

2 days in-company course

Choose date and sign up

Hillerød 31. dec – 31. dec. 2040

Target group

Newly employed academics working in sterile manufacturing, such as chemists, support staff, QA professionals, team leaders and coordinators, who want up-to-date knowledge of Annex 1 and sterile processes.

What you gain

Benefits for employees

- You can navigate Annex 1 and apply its requirements in practice.
- You can use risk management and CCS to prevent contamination.
- You understand why mindset and working practices are crucial for sterile products.

Benefits for the organisation

- Employees are familiar with the requirements for the manufacture of sterile medicinal products.
- Employees have strengthened their understanding of environmental monitoring and contamination control.
- Employees understand the technologies behind RABS, isolators, UDAF and HVAC.

Course program

The course is a 2-day course.

Day 1: 09:00–16:00

- Annex 1 – Regulatory framework
- Aseptic manufacturing
- Facilities and cleanrooms
- CCS and risk management

Day 2: 09:00–16:00

- Microorganisms in the manufacturing environment
- Behaviour, personal hygiene and gowning
- Cleaning, disinfection and sterilisation
- Environmental monitoring and media fills