Manufacturing Sterile Products

Delivery: Classroom, Online, In-house **Duration:** 2 day **Cost:** £1560 (+ VAT)

Course overview

This course provides an extensive introduction to the regulatory requirements governing pharmaceutical clean room operation, and details the aseptic filling and terminal sterilisation methods for producing sterile products. The delegates will gain an appreciation of the significance of sterile products to the patient, and understand why there is intensive regulatory interest worldwide in the control of sterile product manufacture.

Who should attend?

This course will provide valuable underpinning knowledge to all personnel working for companies responsible for the manufacture of sterile products. It will be of benefit to those working in sterile products manufacturing, QC (especially environmental monitoring personnel), QA personnel as well as support engineers.

Course programme

This course includes the following topics:

- Preparing for regulatory inspection
- Basic microbiology
- Contamination control and clean room design
- Steam sterilisation
- Kinetics of steam sterilisation
- Other sterilisation methods
- Microbiological environmental monitoring
- Media fills
- Testing of sterile products

Learning outcomes

At the end of the course you will:

- Understand the risks associated with sterile products
- Appreciate the requirements for contamination control and how this links to clean room design
- Understand the methods for terminal sterilisation and processes involved in aseptic product manufacture
- Appreciate the importance of people and the need for trained personnel

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