Critical Factors for Sterile Product Manufacture
Overview

This course covers all key aspects of sterile product manufacture, for both aseptically prepared and terminally sterilised products.

Open discussion sessions on current best practices and regulatory trends in sterile product manufacture will be coupled with case studies to illustrate key points. All of the course lecturers are actively involved in the industry today and base their lectures on their current knowledge, feedback from recent inspections and today's technology, allowing for the inclusion of practical examples and real life case studies in the course.

CRITICAL FACTORS FOR STERILE PRODUCT MANUFACTURE

Who Should Attend?

All staff, supervisors and managers involved in production including;

- QA, QC,
- engineering, validation
- Regulatory affairs

Course Objectives & Learning Outcomes

- Review the key activities and processes which are critical to the success of sterile manufacturing operations
- Have been refreshed on the special nature of sterile products and understand the challenges involved in aseptic processing and the consequences of failure
- Be able to develop risk assessment methods and quantify risk
- Be able to apply risk management techniques to control contamination in cleanrooms
- Understand how the key aspects of the facility design, personnel, material flows and aseptic control within the cleanroom behaviours determine the success of aseptic processing
- Know how to implement and perform a successful aseptic validation program including practical trial design
- Understand the current sterilisation and sanitisation processes and controls
- Recognise the importance of critical utilities in sterile product manufacture including steam, high purity water and compressed gases
- Appreciate the role of QC laboratories in sterile processes and the role of the QP in sterile manufacture
- Be able to review the current regulatory requirements and trends in sterile manufacture
- Understand common GMP deficiencies and what inspectors are
CRITICAL FACTORS FOR STERILE PRODUCT MANUFACTURE

Course Programme

Day One
Risks in Sterile Product Manufacturing, Bioburden Microbiology, Bioburden Control Sterilisation Steps, Principles of Viable Particle Monitoring (EM), Bioburden Control - Irradiation, Sterile Product Manufacturing Facility Overview.

Day Two

Day Three
Introduction to Cleanrooms, HVAC Systems, Cleanroom Design, RABS & Isolator Technology, Non-Viable Particle Monitoring, Cleanroom Classification & Monitoring, People as a Source of Contamination, Cleanroom Garments for Effective Contamination Control.

Course Programme

Day Four
Aseptic Validation, PST Workshop, HEPA Filters, HEPA Filter Failure Workshop, Product & Equipment Preparations EU/China and US Aseptic Processing Guidelines.

All courses can be booked online:

- Cleanrooms: Principles in Practice®
- Pharmaceutical Water Systems
- Microbiology for Non-Microbiologists
- Sterile Product Manufacture
- Cleaning Validation
- Pharmaceutical Sterilisation
- Microbial Risk Management In Cleanroom Operations
- Biotechnology: Principles in Practice®