honeyman TRAINING

Critical Factors

For Sterile Product Manufacture

Critical Factors for Sterile Product Manufacture

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4 Days Training
Face-to-face at Barnard Castle, UK

18 - 21 June 2024

Who Should Attend?

This course is suitable for all levels of experience and often includes members of the following departments:

- New Graduates
- Operational / Production Supervisors & Managers
- Technical/ Process Team Members
- Engineering & Validation Team Members
- QP's and QA Professionals.

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

This face-to-face course has been designed to provide a comprehensive overview of the critical factors to consider for the preparation of aseptically filled and terminally sterilised products. The course considers the cGMP requirements defined in Annex 1 including the development of a contamination control strategy and introduces risk management tools which have been designed to control microbial contamination in the cleanroom environment, with special consideration to protection of the product. The course is presented using a blended learning approach consisting of interactive presentations, team-based workshops designed to allow our delegates to put the principles into practice as well as a physical review of a state-of-the-art sterile product manufacturing facility.

Course Objectives & Learning Outcomes

On completion of the course our delegates will

•Understand the fundamental mechanisms of microbial contamination transfer within the facility and the control measures in place to protect the product.

•Have reviewed the development of the US and EU GMP regulations and ISO guidelines associated with cleanroom design and monitoring as well as review of current requirements.

•Understand the critical control points within a typical aseptic processing operation with focus on RABS and Isolator technology, Liquid & Air Filtration, Sterilisation & Decontamination steps.

•Understand how Cleanrooms are classified with practical examples on how to meet current ISO requirements and interpretation of the cGMP requirements as defined in Annex 1.

•Have participated in workshops to define practical Process Simulation Test for aseptically filled products.

•Understand the key differences between manufacturing operations designed for manufacture of aseptically filled and terminally sterilised products.

•Understand common cGMP deficiencies in sterile product manufacturing operations and what regulatory health inspectors are looking for.

Course Programme

Honeyman is renowned for industry leading GMP knowledge-transfer, lectures, consultancy and courses, delivered online and in-person.

DAY ONE

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

Filtration of Liquid and Air, Critical Utilities - Water & Steam systems, Moist Heat Sterilisation Porous Loads, Dry Heat Depyrogenation, Steam In Place Systems, Irradiation Methods, VHP Decontamination.

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.

DAY FOUR

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

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