honeyman TRAINING

Aseptic Processing

Principles in Practice®

Aseptic Processing Principles in Practice®

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3 Days Virtual Training

Who Should Attend?

This course is suitable for all members of staff working with aseptic processes, including:

- QP's & Quality
- Operational Managers
- Operations Personnel
- Technical
- Engineering
- Validation

We guarantee on completion of this course that you will look at aseptic processing from a new perspective.

Sterility of an aseptic product cannot be determined by direct assessment of the finished product. Microbiological safety of the product can only be achieved by careful assessment of the hazards and control measures in place to provide the confidence that items are safe for the patient and fit for use.

Historically aseptic processes have relied heavily on monitoring of the environment, air, surfaces and personnel to verify the success of the process. However modern aseptic processes require a more holistic assessment of all the protective measures in place within the process and the complex interactions between these control measures, this approach is fully covered within this course.

Course Objectives & Learning Outcomes

- To understand the fundamental mechanisms of contamination transfer from source to product and the protective measures in place to prevent product contamination.
- To have the opportunity to work with risk management techniques like HACCP and RMC through practical workshops.
- To introduce new thinking for validation and risk assessment of the process.
- To understand the technology associated with cleanrooms and aseptic processes and understand the key control measures and they impact the sterility assurance of the product.
- To understand the cGMP regulations and guidelines for aseptic processing and to engage in discussions regarding industry changes and best practice.

"Excellently delivered, strongly recommend,
the training material is invaluable"
- Specialist QA/QP
Amgen (Technology) Ireland

Course Programme

- Risk Assessment in Aseptic Processing,
  HACCP and RMC Techniques

- Pharmaceutical Microbiology

- Environmental Monitoring
  Viable, Non-viable particles

- Bioburden Control & Sterility Assurance

- Methods of Sterilisation
  Moist Heat (Porous loads, SIP), Filtration, Dry Heat

- Methods of Decontamination - VHP

- Clean Utilities - WFI

- Cleanroom Design and Operation

- HEPA Filters

- RABS & Isolator Technology

- People as a Source of Contamination

- Effective Contamination control

- Aseptic Validation

- Process Simulation Tests

- Aseptic Processing Guidelines and Regulations

- Regulatory Trends and Interpretations

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