honeyman
TRAINING

Sterilisation

Principles in Practice®

Pharmacuetical Sterilisation Principles in Practice®

Click for full details

3 Days Virtual Training

Who Should Attend?

The course is regularly attended by:

- Engineers
- Microbiologists
- QA & QC Personnel
- Production
- Operational
- Technical Personnel

This course provides delegates with a comprehensive understanding of moist heat and dry heat sterilisation processes from theoretical foundation through to the practical aspects of validation and biological indicators.

The course highlights the GMP requirements and current industry expectations for the routine operation, monitoring and control of sterilisation processes and gives practical examples of how these techniques are applied through appropriate engineering to ensure reliability in full compliance with all European and US regulatory requirements.

Course Objectives & Learning Outcomes

- To have increased awareness of the development of the current regulatory requirements and standards for sterilisation processes and how this has shaped the way the industry approaches sterilisation.
- To be able to make risk-based decisions based on science during the qualification and routine operation of sterilisation processes.
- To be able to drive sterilisation process improvement initiatives in the workplace and improve compliance for sterilisation processes.
- Be able to implement value adding test plans for Equipment Qualification based on science, experience and compliance with GMP principles.
- To participate in the most up to date review of future international sterilisation standards and changes to the Pharmacopoeias.
- Understand the Auditing Sterilisation Processes and Preparing for a Regulatory Inspection.
- Understand the reasoning behind the use of Biological Indicators.
- Understanding of Routine Operation of Sterilisers.
- Understand the different challenges of sterilising porous, liquid and heat sensitive products.

“ This course includes a combination of Presentations, Workshops, Group Activities and Demonstrations to allow you to put the Principles into Practice®”

> Highly recommend this course to anyone who works in the pharmaceutical industry producing sterile products.
> Microbiology Team Manager,
> GSK

Course Programme

- Development of Current Sterilisation Standards Regulations and Guidance including Future Requirements
- Principles of Moist Heat Sterilisation
- Lessons learnt from the Devonport Incident
- Steam Quality Generation Distribution and Use
- Porous Load Sterilisation, Air Detectors and EN285
- Terminal Sterilisation of Fluids and Qualification Strategies
- Dry Heat Sterilisation, Depyrogenation and the application of EN20857
- Instrumentation and Control of Sterilisation Processes
- Steam In Place Design, Operation, Validation, Control
- Risk Assessment Workshops for Sterilisation processes Including selection of worst case load items for Validation
- Quality System Requirements to ensure compliance with GMP requirements for sterilisation processes
- Auditing Sterilisation Processes and Preparing for a Regulatory Inspection
- Application of risk assessment during sterilisation equipment lifecycle Validation
- Use and Application of Biological Indicators (D-Value, Z Value, Organism selection, D value Determination)
- Validation Strategies for Sterilisation Processes (Overkill, Bioburden, BI/Bioburden)
- Qualification activities including URS, DQ, FAT, IQ, OQ, PQ and Requalification
- Cycle Development and Performance Qualification
- Process improvement for Routine Operation of Sterilisers and hazard analysis
- Continual Compliance Assurance

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