

Sterilisation and Depyrogenation

Overview

Many of the critical control points associated with sterile product manufacture are associated with sterilisation and depyrogenation processes; autoclaves, steaming in place systems, depyrogenation tunnels and ovens are key to delivery of the overall process sterility Assurance level.

In addition EU GMP Annex 1 and EN285 have some very specific requirements related to these subjects.

This course has developed over many years and is constantly being updated as technology and regulatory expectations progress. Lectures include numerous case studies and relevant examples to help provide practical application of the subject.

Course duration is between 2 and 4 days, dependent upon the depth, scope and site technologies involved.

Target audience

This course will benefit all involved in sterilisation and depyrogenation.

The course goes to SME level with ongoing consultancy support following the training as required.

About the Lecturer

This course is delivered by Mark Thompson who has been delivering training and consultancy in sterilisation and depyrogenation for the past 19 years.

Mark has delivered this training course to many of the worlds inspectorates and written inspection guidelines for some.

Recent Comments

"This course has delivered a plan for process improvements in terms of efficiency and solving long standing problems – Highly recommended"

"Mark's knowledge of this subject is very impressive, the constant examples and case studies makes the course completely engaging"

"We have completed this 4 day SME training with SME level knowledge and a detailed action plan for the site "

| Consultancy & training in sterile product manufacture |
| T: +44 (0)7780 430383 |

Course Programme

DAY 1:

- The Spectrum of Sterilisation (Sanitisation, Bioburden Control and Sterilisation)
- Sterility Assurance Levels
- Current Regulatory Framework and Key Standards. (From HTM2010 to EN285 and PDA Technical Reports)
- Introduction to Microbiology – Pyrogen Control, Sterility Assurance
- Kinetics of Death, Moist Heat and Dry Heat
- Steam Quality Requirements
- Steam Quality Testing (NCG, Dryness and Superheat)
- Wet Steam Case study.
- Equipment and Porous Load Sterilisation
- Porous load cycle development for air removal and load dryness

DAY 2:

- Porous Load Benchmark Challenges from EN285
- Application of EN285 acceptance criteria
- Equilibration Time Case Study
- Air Detector Installation, Set-up and Performance Testing
- Wet Loads Case Study and Investigations
- Steaming in Place – Sanitisation, Bioburden Control and Sterilisation
- Fluid Loads Sterilisation – Steam, Air/Steam, Water Spray and Water Cascade
- Monitoring Fluid Load Sterilisation Processes
- Additional considerations for Terminal Sterilisation
- Dry Heat for Sterilisation and Depyrogenation
- Batch Ovens and Tunnel Ovens

DAY 3:

- Depyrogenation Tunnel Cleaning, Filter Testing and Sanitisation.
- Cycle Development and Load Definition for Process Efficiency
- Criticality Assessment of Acceptance Criteria
- Performance Qualification and Re-Qualification Approaches
- Thermal qualification requirements; measurement and data logging options).
- Biological Challenges; Pharmacopeia requirements for BI's
- BI receipt verification, storage and use.
- Operation, Routine Monitoring and Testing Reviewing Cycle Data, Use of Independent Records, Electronic Data Storage
- Requalification trends and Annual QA Review, including the role of the Subject Matter Expert

NOTE : Above example programme can be tailored to site specific needs, technologies and regulatory requirements.

Sterilisation and Depyrogenation Training delivered on your site is generally tailored to the specific loads, sterilisation processes, autoclaves, tunnels and any current issues.

The Course can be structured so that the first two days are relevant to everyone involved in sterilisation and the third / fourth day is focused on technical, validation and QA detail.

Subject Matter Expert Training is structured around defined learning objectives and measurable learning outcomes.