MARKTHOMPSON
LIFESCIENCES

Advanced Sterilisation Validation

Overview

This advanced course assumes a good working knowledge of the operation of moist heat sterilisation processes. Often this is used as a follow on course after the sterilisation and depyrogenation 3 day course.

The course describes the validation approach from concept through to production and ongoing requalification. There is a considerable amount of the course dedicated to cycle development, as required by Annex 15, qualification. The limits of operation should be challenged and these limits should be established and understood through the commissioning (cycle development) stage. It is much easier to validate a cycle that works than a cycle that is unreliable or on the point of failure, cycle development delivers this!

The course covers all aspects of thermal and biological qualification, execution, data analysis and sterility assurance calculations.

Target audience

The course is designed for validation technicians, engineers and QA currently involved and responsible for qualification of sterilisation processes.

The course includes details on biological challenges (BI's and inoculation) which would be of interest to the microbiologists involved in BI receipt, verification, control and analysis.

About the lecturers

All courses are led by Mark Thompson who delivers the majority of lectures. Mark has over 27 years of pharmaceutical industry experience and has been delivering training and consultancy to the industry for the past 19 years.

Mark has worked with and trained people all over the world, including many regulatory inspectorates. When the Chinese FDA introduced their new GMP's in 2011, Mark was asked to deliver training and write an inspection g¬uide (which can be downloaded from the resources section).

| Consultancy & training in sterile product manufacture |
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Course Programme

DAY 1:

- The regulatory framework, standards and guidance documents
- The spectrum of sterilisation and defining system Impact assessment
- Cycle development objectives and acceptance criteria
- Cycle design and cycle development for:-
  - Gravity displacement
  - Porous loads / equipment / wrapped loads
  - Air detector
  - Fluids loads
  - Balanced pressure fluids loads
- Routine monitoring and data review*
  - Leak testing (vacuum and pressure requirements)*
  - Bowie dick type test pack*
  - Air detector testing*
  - Data review, independent data, PT correlation*

DAY 2:

- Autoclave checks prior to qualification starting
- Thermal monitoring systems, options, pros and cons
- Locating temperature probes within the load*
- Biological challenges, receipt verification and specification
- Locating biological challenges in a representative manner*
- Establishing CQA's and process limits
- Documenting the cycle development phase
- Benchmark testing requirements
  - Empty chamber testing
  - EN285 small load pack testing*
  - EN285 air detector (Including specific MHRA and HPRA requirements)*

DAY 3:

- PQ Protocols
- Sterility assurance level calculations and methods
- Overkill sterilisation cycles
- BI / bioburden sterilisation cycles
- Calculation of FPhys and FBio
- Linking physical and biological data
- Handling deviations during PQ execution
- The PQ report
- Defining requalification scope and frequencies
- Annual review, data review and trending
- Regulatory feedback, current inspection trends

NOTE :

As with all courses the content if often tailored to specific site requirements. In some cases access to an autoclave, loads and thermal monitoring equipment is made available so that some of the sections can be implemented as a practical session. These are highlighted with * above.