MARKTHOMPSON
LIFESCIENCES

Sterile Product Manufacture

Overview

This course has been developed based upon current technologies and industry trends. Mark Thompson Lifesciences are actively involved in projects around the world dealing with today's technology and current regulatory expectations. This current project involvement ensures that the training delivered is as up to date and relevant as possible.

This diverse and comprehensive course delivers a summary of all aspects required for Sterile Product Manufacture, and can be tailored to your unique market sector or product portfolio.

The course is a must for anyone new to the industry, people wanting a refresher on returning to work, or used as part of a GMP site wide programme.

Target audience

This course will benefit professionals new to Sterile product manufacture as well as experienced individuals wanting to benchmark with the industry and gain an insight into current regulatory expectations.

"I have worked in Sterile manufacture for 12 years and this is the best course we have had, both lecturers have such a vast experience. Great to know what the rest of the industry is doing!" Helen O, QA Ops Lead

Application of Knowledge

Information is only a click away on any subject. Internet content, webinars, on line 'training' etc. In many cases there is information overload, and contradiction. Intelligent Application of this readily available information is where Mark Thompson Lifesciences can help.

About the Lecturers

Dependent upon the final content of the training g course agreed this course is delivered by between 2 and 4 people. All of the Associates who work with mark Thompson Lifesciences are actively engaged in the Pharmaceutical Industry ensuring information is current and reflects Industry best practice as well as regulatory trends and expectations.

"The case studies presented are so relevant to our current issues. Comforting to know the rest of the industry is struggling, even better to find out the solution to our current issues!! Chris T, Validation Engineer

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Course Programme

DAY 1: Expectations for Sterile product manufacture

- The spectrum of sterilisation and process risk assessment
- Current regulatory framework and emerging standards
- Quality critical attributes
- Regulatory framework
- Industry guidance, documents and trends
- Manufacturing process flows (aseptic / terminal)
- Introduction to microbiology
- Microbiological spectrum (sources of contamination and virulence factors)
- Monitoring (RM, environment, product)
- Testing and Identification
- Limits and trending. Using the data
- Objectionable organisms and investigations

DAY 2: The Manufacturing Environment

- Objectionable organisms and investigations.
- Requirements for air quality
- ISO and EU standards and guidance documents
- Clean room design (construction, layout, surface finishes)
- Viable and Non-viable limits and monitoring
- HVAC design (air flows, parameters, validation and testing)
- Operating in a Clean Room, Gowning and behaviour
- Material air locks (MAL's) and personnel air locks (PAL's)
- Material and people flows, risk assessments and controls.
- Cleaning and disinfection of clean rooms
- Interpretation of data and the test technicians report

DAY 3: Technical Support Services

- Critical utilities
- Water and steam
- Compressed air and critical process gases
- Good engineering practice
- Maintenance and calibration
- Critical alarm testing
- Software validation (GAMP5 guidance)
- Data integrity (21cfr11 compliance)
- Control of contractors
- Technical agreements
- Qualification and validation
- Disaster recovery expectations and planning

DAY 4: Bioburden Control, Sanitisation and Sterilisation

- Bioburden control from RM to finished product
- CIP and COP systems
- SIP and SOP systems
- Porous and fluid load sterilisation
- Depyrogenation
- Filtration and filter integrity testing
- Control of contract sterilisation services (Gamma and EtOx)
- UV, VHP and E beam processes

DAY 5: Quality Systems, Audit and Review

- Role of QC, QA and the QP
- Change control
- CAPA
- Risk assessments and criticality assessments
- HACCP and FMEA
- Self-inspection
- Annual review
- Regulatory communications and Inspections
- Course Assessment