SQT

TRAINING THAT DEVELOPS *REAL* CAPABILITY











Fundamentals of Sterilisation Validation for Single Use Medical Devices

LS029

Fundamentals of Sterilisation Validation for Single Use Medical Devices

Ethylene Oxide sterilisation is commonly used to terminally sterilise single use medical devices. The increasing regulatory and compliance requirements in the management of sterilisation processes places additional demands on project teams including those involved in the design and development of new innovative products as well as those involved in operational and supply chain improvements and efficiencies. This one day course details the compliance requirements and the current industry best practice approaches to validation and product testing using practical examples.

It is designed to provide a comprehensive knowledge of an EO sterilisation validation process, which delivers the required Sterility Assurance Level, Microbiological Performance Qualification and Physical Performance Qualification to ensure repeatability of the routine processing. The course also addresses and explains associated product testing and test method validation for bioburden, product endotoxin, test of sterility, bacteriostasis & fungistasis and residuals.

The course explains the impact of design and manufacturing changes on the sterilisation process, associated product testing and gives examples of how these may be assessed and managed through the validation and change control processes. Sterilisation processes are audited regularly by Regulatory Bodies and this course will give a background for preparing for a regulatory inspection. Routine management of the sterilisation process from pre-sterile checks to defining a product release process will be addressed.

This course is available exclusively on an In-House basis

Duration & Price

Duration: 1 day
Delivery mode: This programme is available In-Company

Dates & Locations

In-Company training programmes are customised for your organisations specific needs. Most In-Company training is now delivered virtually.

In-Company Training

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What's covered?

- Explanation of the EO sterilisation processes.
- Microbiological and Physical Performance aspects of sterilisation validations.
- Responsibilities of all the stake holders; design team, manufacturers, laboratories and sterilisation sub-contractors.
- Product testing and test method validation.
- Assessment of process and product changes
- Regulatory requirements and how to prepare for a regulatory audit.
- Process validation – different approaches that may be used.
- Management of routine sterilisation cycles, product release and process deviations.

Who should participate?

Sterilisation validation requires Microbiology, R&D, Engineering, Packaging, Quality, Operations and Regulatory inputs to ensure the validated process is suitable for routine use, changing supply chain requirements while meeting compliance requirements. As most companies use contract sterilisation contractors, this course helps customers to engage with their sterilisation sub-contractors to develop compliant while cost effective validation strategies.

• R&D engineers
• Operations
• Regulatory
• Microbiologists
• Quality
• Technical

What will I learn?

Participants achieve the following learning outcomes from the programme;
• Identify industry best practices and regulatory compliance requirements and demonstrate these sterilisation projects.
• Plan the requirements of an EO sterilisation validation and related product testing, including EO Requalification activities.
• Develop and communicate validation strategies with internal teams and sterilisation sub-contractors.
• Analyse and Interpret validation results.
• Assess the effects of product and packaging design & manufacturing changes on an existing sterilisation process and product testing.
• Evaluate validation documentation for a regulatory inspection and continued quality compliance.
• Generate requirements to support Product Release Activities

Tutors



Maura Walsh
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What Our Learners Say

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- Lean Six Sigma
- Join our Lean Six Sigma Network
- Continual Process Improvement
- Project & Programme Management

COMPLIANCE, STANDARDS & AUDITING

- Quality
- Environment & Energy Management
- Health & Safety
- Food Safety
- Life Sciences
- Laboratory
- Integrated Management Systems

LEADERSHIP & PERSONAL DEVELOPMENT

- Leadership & Personal Development
- Train the Trainer

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