











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**

Please contact us for more information on our In-Company training options

#### 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.

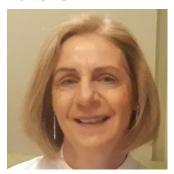
- R&D engineers
- Operations
- Regulatory
- Microbiologists
- Quality
- Technical

#### 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 subcontractors.
- 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 View Profile

## **What Our Learners Say**

We believe in excellence through transparency and continuous improvement. That's why we invite all our delegates to share their experiences on <a href="CourseCheck.com">CourseCheck.com</a>, an independent platform dedicated to genuine, unfiltered feedback. Learner insights help us not only to enhance our training programmes but also empower potential learners to make informed decisions. Click on the link below to read firsthand experiences and testimonials from past learners.



**Click Here** 



SQT provide a unique combination of high quality, accredited, practical training delivered by leading industry experts and supported by the most up to date learning technology and tools

## LEAN SIX SIGMA, PROCESS & PROJECT MANAGEMENT

- 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
- <u>Integrated Management</u> Systems

#### LEADERSHIP & PERSONAL DEVELOPMENT

- Leadership & Personal
  Development
- Train the Trainer













SQT Training Ltd. | T: +353 61 339040 | E: info@sqt-training.com W: sqt-training.com





Please follow us on social media for relevant news, events and updates