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Management Forum

# An Introduction to Ethylene Oxide (EO) Sterilization for Medical Devices

11 November 2024

Sterile devices are free of viable microorganisms and EO sterilization is one of the key processes in the production of sterile medical devices. This course provides an introduction to the regulatory requirements as they relate to EO sterilisation and how manufacturers may demonstrate compliance.



**Format:**  
Live online



**CPD:**  
3 hours for your records



Certificate of  
completion

# Overview

## **Sterile devices are free of viable microorganisms and EO sterilization is one of the key processes in the production of sterile medical devices.**

Regulations for medical devices include particular requirements for devices supplied or intended to be used in a sterile state. These regulatory requirements relate to general safety and performance aspects for the products, and the requirements for independent, third-party conformity assessment of the processes for achieving sterility. Evidence of successful sterilization by Ethylene Oxide is important and expected when demonstrating conformity with the regulations.

These requirements have been supported by a portfolio of standards on:

- Designating products as sterile;
- Validating and routinely controlling the sterilization process;
- Determining whether the sterilization process has any adverse effect on the devices; and
- Maintaining sterility over time with appropriate sterile barrier systems

This course provides an introduction to these regulatory requirements as they relate to EO sterilization and how manufacturers may demonstrate compliance.

### Benefits in Attending

- **Gain** an overview of medical device sterilization by EO
- **Understand** the principles of EO validation for medical devices
- **Learn** the regulatory requirements for EO sterilization and how to comply
- **Gain** an awareness of supporting standards and their interrelationships

### Who Should Attend

- Microbiologists and sterilization professionals
- Quality Management System (QMS) specialists
- Regulatory Compliance specialists
- Internal Auditors
- Regulatory and Quality professionals

**Please note** that delegates will require access to a copy of ISO 11135 to gain the most from this training. If you do not already have access to this through your organisation, please see below the ways to acquire it:

ISO 11135  
- <https://www.iso.org/standard/56137.html>

This standard is also available from national standards organizations such as BSI, DIN, AFNOR, AAMI, NSAI, etc

# Programme

## **Ethylene Oxide Sterilisation Principles**

- Background and the ISO 11135 standard
- Microbiocidal principles of ETO
- ETO sterilisation process stages and critical parameters
- Product characteristics affecting / affected by ETO

## **Validation of Ethylene Oxide Sterilisation Installation and Operational Qualification (IQ & OQ)**

- Microbiological performance qualification (MPQ)
- Use of biological and chemical indicators
- Physical performance qualification (PPQ)
- Product adoption into existing validations – ISO 11135 and AAMI TIR 28

## **Routine Monitoring and Control**

- Product release from sterilisation
- Assessment of change and revalidation
- Bioburden monitoring and ISO 11737-1

## **Ethylene Oxide Residual Control and Testing**

- Establishing limits – ISO 10993-7
- Testing process and considerations
- Product release considerations

# Presenter



## **Annette Callaghan**

A quality management professional, chartered biologist and member of the Royal Society of Biology, with over 35 years' experience in the medical device, pharmaceutical, biotechnology and food industries. Extensive knowledge of quality and environmental management systems, internal and third-party auditing and personnel training. Eligible to act as a Qualified Person as defined in Directive 2001/83/EC, as amended (previously 75/319 et al.) since 1993. A Qualified Notified Body Lead Auditor since 2002 (IRCA ref: 1182641).

# Course date

11 November 2024

Live online

13:30-17:00 **UK (London)** (UTC+00)

Course code 14310

GBP ~~299 349~~

EUR ~~429 499~~

USD ~~501 579~~

Until 07 Oct

## How to book



**Online:**

[ipi.academy/2693](https://ipi.academy/2693)

Alternatively contact us to book, or if you have any queries:



**Email:**

[info@ipi.academy](mailto:info@ipi.academy)



**Phone:**

[+44 \(0\)20 7749 4749](tel:+442077494749)

## Discounts

- Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

## Further information

### Fee

The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

### Please note

IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

### Terms and conditions

The rest of our terms, the event cancellation policy and the terms and conditions are on our website, please visit [ipi.academy/content/terms-and-conditions](https://ipi.academy/content/terms-and-conditions)

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**ALEKSANDRA BEER**

**Tel:** +44 (0)20 7749 4749

**Email:** [inhouse@ipi.academy](mailto:inhouse@ipi.academy)



**YESIM NURKO**

**Tel:** +44 (0)20 7749 4749

**Email:** [inhouse@ipi.academy](mailto:inhouse@ipi.academy)



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10-12 Rivington Street  
London EC2A 3DU

[ipi.academy](http://ipi.academy)

**Tel:** +44 (0)20 7749 4749

**Email:** [info@ipi.academy](mailto:info@ipi.academy)