IPI Academy

MANAGEMENT forum



Presented by
Management Forum

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

13 May 27
+ 8 November 27

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

Course 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 of 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 dates

13 May 27	**Live online** 13:30-17:00 **UK (London)** (UTC+01) *Course code 17178*	GBP **350** ~~400~~ EUR **490** ~~560~~ USD **562** ~~640~~ **Until 18 Mar**
8 November 27	**Live online** 13:30-17:00 **UK (London)** (UTC+00) *Course code 17465*	GBP **350** ~~400~~ EUR **490** ~~560~~ USD **562** ~~640~~ **Until 13 Sep**

How to book

Online:
ipi.academy/2693

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

Email:
info@ipiacademy.com

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **30% 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 the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Reviews

★★★★★

Excellent - very informative and managed to pack a lot into a half day training session. I thought [speaker] was a great presenter and clearly had deep knowledge of the subject matter.

Vikki Young
Head of Quality and Regulatory
Prothea Technologies
Nov 11 2024

Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:



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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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