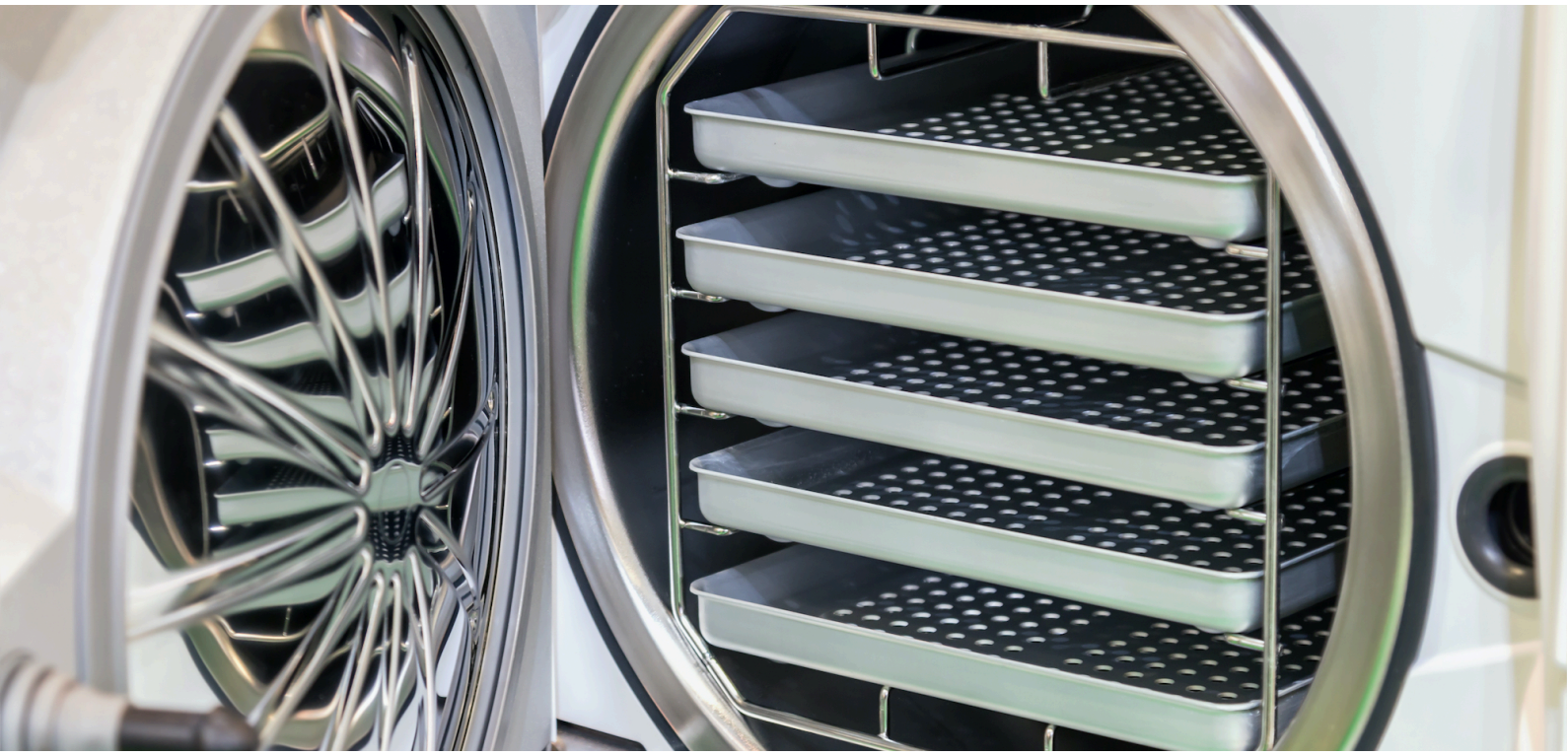
IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Sterilization of Medical Devices

16-17 October 2025

Sterile devices are free of viable microorganisms and 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 is important and expected when demonstrating conformity with the regulations. This course provides a comprehensive overview of these regulatory requirements and how to comply, together with the science and standards that support them.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Overview

Sterile devices are free of viable microorganisms and 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 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; and
- Maintaining sterility over time with appropriate sterile barrier systems

This course provides a comprehensive overview of these regulatory requirements and how to comply, together with the science and standards that support them.

Please note that delegates will require access to copies of ISO 11135 and ISO 11137-1 in order to take part in the exercises. If you do not already have access to these through your organisation, please see below the ways to acquire them:

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

ISO 11137-1 - https://www.iso.org/standard/33952.html **and amendment at** https://www.iso.org/standard/72106.html

These standards are also available from national standards organizations such as BSI, DIN, AFNOR, AAMI, NSAI, etc.

Benefits of attending

- **Gain** a comprehensive overview of medical device sterilization
- **Recognise** the principles of the commonly applied methods of sterilization
- **Learn** the regulatory requirements for sterilization and how to comply
- **Understand** the portfolio 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

Programme

Day 1

Introduction and welcome

The use of standards and overview of standards for sterilization

- Role of standards
- Interaction of standards and regulations for medical devices
- Portfolio of sterilization standards

General requirements

- ISO 14937 - Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
- Structure of sterilization standards
- Common features of validation and routine control

Microbiology quality

- Introduction to microbiology
- Sources of microbial contamination
- Contamination control

Microbiology methods

- Bioburden estimation – EN ISO 11737-1 Sterilization of medical devices – Microbiological methods - Part 1: Determination of a population of microorganisms on products
- Test of sterility – EN ISO 11737-2 Sterilization of medical devices – Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

Microbial inactivation

- Inactivation kinetics
- Sterility assurance
- EN 556-1 Sterilization of medical devices – Requirements for a terminally-sterilized device to be labelled “Sterile”

Sterilization by irradiation

- Nature of ionizing radiation
- Sources of ionizing radiation
- Measurement of radiation dose
- Installation Qualification, Operational Qualification and Performance Qualification
- EN ISO 11137-1 1 Sterilization of health care products - Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- EN ISO 11137-3 Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control
- EN ISO 11137-4 Sterilization of health care products — Radiation — Part 4: Guidance on process control

Q & A

Day 2

Introduction and recap of day one

Sterilization by irradiation (cont.)

- Establishing the sterilization dose
- EN ISO 11137-2 Sterilization of health care products - Radiation – Part 2: Establishing the sterilization dose
- ISO/TS 13004 Sterilization of health care products - Radiation - Substantiation of selected sterilization dose: Method VD_{max}^{SD}

Biological indicators

- EN ISO 11138 series - Sterilization of health care products — Biological indicators

Syndicate exercise - Radiation sterilization

- Feedback and discussion

Ethylene oxide sterilization

- EN ISO 11135 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices

Ethylene oxide sterilizaton (cont.)

- EN ISO 11135 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices

Syndicate exercise - Ethylene oxide sterilization

- Feedback and discussion

Moist heat sterilization

- EN ISO 17665-1 Sterilization of health care products - Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

Wrap up and Q & A

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

16-17 October 2025	**Live online** 09:30-17:30 **UK (London)** (UTC+01) *Course code 15022*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 11 Sep**

How to book

Online:
ipi.academy/2616

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

★★★★★

This was an excellent webinar. Very useful and [speaker] has a lot of knowledge and experience, giving us examples from real life, making the concepts easier to understand and the course more enjoyable, was fantastic - kept me engaged the entire time. Very well organized.

Maria Jesus Lopez Villanueva
QA Administrator Eng
Endomag
Feb 3 2025

★★★★★

[Speaker] very experienced, knowledgeable and approachable. Webinar [was] prepared taking into account all of the participants with the general information as well as with the direct individual requirements in mind. Questions answered at the time as well as within time given after the webinar. Thank you.

Dorota Seweryn
Quality Engineer
First Water Ramsbury Limited
Oct 17 2024

★★★★★

The Speaker was very knowledgeable and the inside stories are great!

Priya Woodun
Senior QA Compliance Officer
Endomagnetics Ltd
Jun 6 2024

★★★★★

Very structured training at perfect pace, covering all important point. Very good interaction.

Marijana Jelecevic Kakouros
RA Manager
Beckton Dickinson
Jun 1 2023

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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