IPI Academy

MANAGEMENT forum

Presented by
Management Forum

An Introduction to ISO 11607 - Packaging for Terminally Sterilized Medical Devices

18 November 2024

Sterile devices are free of viable microorganisms and the sterile barrier system is the key to maintaining this sterility until the medical device is ready to be used on a patient. This course provides an introduction to the regulatory requirements as they relate to typical sterile barrier systems used for single-use and reusable medical devices, 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 the sterile barrier system is the key to maintaining this sterility until the medical device is ready to be used on a patient. Regulations for medical devices include particular requirements for devices supplied or intended to be used in a sterile state, including maintaining this state for a defined period of time. These regulatory requirements relate to general safety and performance aspects of the products, and the requirements for independent, third-party conformity assessment of the processes for achieving and maintaining sterility. Evidence of an appropriate and stable sterile barrier system is important and expected when demonstrating conformity with the regulations.

These requirements are supported by a series of standards for maintaining sterility over time with appropriate sterile barrier systems.

This course provides an introduction to these regulatory requirements, as they relate to typical sterile barrier systems used for single-use and reusable medical devices, and how manufacturers may demonstrate compliance.

Benefits of Attending

- **Gain** an overview of the types of sterile barrier systems used for medical devices
- **Understand** the principles of sterile barrier system validation
- **Learn** the regulatory requirements for sterile barrier systems and how to comply
- **Gain** an awareness of the ISO 11607 series of standards

Who Should Attend

- Quality Management System (QMS) specialists
- Quality, Packaging and Validation Engineers
- Regulatory Compliance specialists
- Internal Auditors
- Regulatory and Quality professionals

Please note that delegates will require access to a copy of ISO 11607-1 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 11607-1
- https://www.iso.org/standard/70799.html

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

Programme

The ISO 11607 Series of Standards

- Background and reference to EN 868 and AAMI TIR22
- Definitions
- Types of packaging systems
- Packaging materials

ISO 11607 Part 1

- General requirements
- Material requirements

ISO 11607 Part 1 (continued)

- Designing a sterile barrier system
- Packaging system performance and stability testing

ISO 11607 Part 2

- Sterile barrier system manufacturing
- Equipment validation
- Process validation
- Process control and ongoing monitoring

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

18 November 2024

Live online
13:30-17:00 **UK (London)** (UTC+00)
Course code 14312

GBP **299** ~~349~~
EUR **429** ~~499~~
USD **501** ~~579~~
Until 14 Oct

How to book

Online:
ipi.academy/2694

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

Email:
info@ipi.academy

Phone:
+44 (0)20 7749 4749

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 the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Run this programme in-house for your whole team

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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:

ALEKSANDRA BEER
Tel: +44 (0)20 7749 4749
Email: inhouse@ipi.academy

YESIM NURKO
Tel: +44 (0)20 7749 4749
Email: inhouse@ipi.academy

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.

10-12 Rivington Street
London EC2A 3DU

ipi.academy
Tel: +44 (0)20 7749 4749
Email: info@ipi.academy