IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Cleanroom Requirements for Medical Device Manufacturers

22 September 2025
+ 23 February 2026, 21 September 2026

This course introduces key regulatory requirements for manufacturing sterile or clean medical devices in controlled environments. It covers standards for ensuring compliance, including environmental controls and third-party assessments.

Format:
Live online

CPD:
6 hours for your records

Certificate of completion

Course overview

Medical devices which will be aseptically manufactured, terminally sterilised or where their cleanliness is of importance in use need to be manufactured under controlled conditions. Regulations for medical devices include particular requirements for devices supplied or intended to be used in a sterile state, including the environmental conditions under which manufacturing and primary packaging should take place. 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 and maintaining sterility. Evidence of an appropriately controlled work environment is important and expected when demonstrating conformity with the regulations.

These requirements are supported by a series of standards on designing, operating, testing and classifying clean environments.
This course provides an introduction to these regulatory requirements as they relate to the design and management of a controlled working environment for the manufacture of medical devices and how manufacturers may demonstrate compliance.

Benefits of attending

- **Gain** an overview of the types of controlled environments used for medical devices
- **Understand** the principles of cleanroom design, validation and ongoing monitoring
- **Learn** the regulatory requirements for controlled environments and how to comply
- **Gain** an awareness of the ISO 14644 and related series of standards.

Who should attend

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

Please note that delegates will require access to a copy of **ISO 14644-1 and EN 17141** to gain the most from this training. If you do not already have access to these through your organisation, please see below the ways to acquire them:

- ISO 14644-1 - **https://www.iso.org/standard/53394.html**
- EN 17141 - **https://knowledge.bsigroup.com/products/cleanrooms-and-associated-controlled-environments-biocontamination-control**

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

Programme

Cleanroom design and operation

- Airflow principles and systems
- Other construction considerations
- Control of people and materials
- Cleaning and monitoring

Cleanroom classification and testing

- Required classification(s)
- Non-viable particle testing
- Other testing / validation requirements

Microbiological monitoring

- Monitoring plan and methods
- Setting warning and action levels
- Investigation and corrective action

Additional considerations

- Chemical contamination
- Aseptic processing

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

22 September 2025	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 16662*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 18 Aug**
23 February 2026	**Live online** 09:30-17:00 **UK (London)** (UTC+00) *Course code 16663*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 19 Jan**
21 September 2026	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 16664*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 17 Aug**

How to book

Online:
ipi.academy/2907

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

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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