IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Biological Evaluation of Medical Devices

20-21 January 27
+ 1-2 July 27

Key guidance on how to use the ISO 10993 series of standards and successfully apply a risk management approach to the biological evaluation of medical devices.

Includes: Interactive workshops and discussion sessions

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

Ensure compliance with the ISO 10993 series of standards for the biological evaluation of medical devices, as it is well-established and expected by regulatory authorities worldwide.

In the European Union, compliance with these standards is crucial for meeting the essential safety requirements outlined in the Medical Device Regulation (MDR). Understanding and implementing a comprehensive risk management strategy for biological safety is therefore paramount.

This course offers essential guidance on effectively utilising the ISO 10993 standards and integrating a robust risk management approach into the biological evaluation process of medical devices. Participants will have ample opportunity to engage in interactive discussions with industry experts, gaining practical insights and best practices.

Attendees will emerge equipped with the knowledge and tools necessary to navigate regulatory requirements, mitigate risks, and ensure the safety and efficacy of medical devices in compliance with global standards.

Benefits of attending

- **Understand** biological risk management
- **Clarify** the requirements of ISO 10993-1
- **Learn** what endpoints need to be addressed in a biological risk assessment
- **Establish** how much chemical characterisation is necessary
- **Explore** the FDA's approach to ISO 10993
- **Comprehend** the Medical Device Directive (MDD) safety requirements vs the Medical Device Regulation (MDR) safety requirements
- **Recognise** how extractables and leachables impact medical device safety
- **Discuss** the Japanese and Chinese requirements

Who should attend

The course will be of particular importance to those in the medical device industry from the following departments:

- Regulatory affairs
- R&D
- Product safety/toxicology
- Analytical chemistry
- Risk assessment and risk management
- Materials research and evaluation

It will also be of interest to regulatory authorities, Notified Bodies and CROs supporting the medical device industry.

Programme

Day 1

Introduction to biological evaluation

Overview of biocompatibility

ISO 10993 history and development / ISO 10993 structure and content

Relationship between regulatory standards

Impact of MDR

Impact of Brexit

Gap analysis of existing biocompatibility data

Medical device categorisation for biological risk assessment

Endpoints to be addressed in a biological risk assessment

GLP requirements

Lab selection

Day 2

Physical and chemical characterisation

Extractables and leachables testing - when and why?

Use of QSAR

Use of data sources to and literature searching

Change management

International requirements

Gas pathway devices

- Practical exercise

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

20-21 January 27	**Live online** 09:00-16:30 **UK (London)** (UTC+00) *Course code 16971*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 25 Nov**
1-2 July 27	**Live online** 09:00-16:30 **UK (London)** (UTC+01) *Course code 17298*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 06 May**

How to book

Online:
ipi.academy/1100

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

★★★★★

Good, very informative and was helpful. Definitely achieved a better understanding of Biocompatibility of medical devices testing and applications.

Nafisa Huq
Global Microbiological Lead
Vernacare International
Jul 13 2026

★★★★☆

It was great; I learned a lot and gained a new perspective. She was very warm and responded well to all questions. Even as a non-native speaker, she was very easy to understand and spoke clearly.

Saskia Willuweit
teamleader for mechatronik development
Brütsch Technology AG
Jul 13 2026

★★★★☆

I had hoped to get a more detailed introduction to creating a BEP/BER and to learn a strategy for avoiding some of the tests. It was great; I learned a lot and gained a new perspective., she was very warm and responded well to all questions. Even as a non-native speaker, she was very easy to understand and spoke clearly.

Saskia Willuweit
teamleader for mechatronik development
Brütsch Technology AG
Jul 13 2026

★★★★★

Content, speaker and presentation were all of a high standard and I came away with a much better understanding of biocompatibility / biological evaluation. The content on chemical characterization was particularly helpful. I was overall very happy with this training course.

Sarah Tait
Regulatory Affairs Manager
Kimal PLC
Jan 15 2025

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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