Irish Medtech Skillnet

Biological Evaluation of Medical Devices

eurofins | Medical Device Testing

Skillnet IRELAND

Irish Medtech Association
Ibec

Introduction

This training course will describe the big-picture concept of biological evaluation of medical devices, providing a wide and comprehensive overview of the main relevant key topics and critical aspects. It offers a first-hand look at how to plan and conduct the biological evaluation, and, more importantly, how such an evaluation sits within the activities of design control and risk management by giving practical hints for the definition of pathways based on scientific rationales.

The course will also give the opportunity to bring your specific questions and case studies along to the course for discussion and to help to determine a resolution in order to enhance the learning experience.

Key Learning Objectives

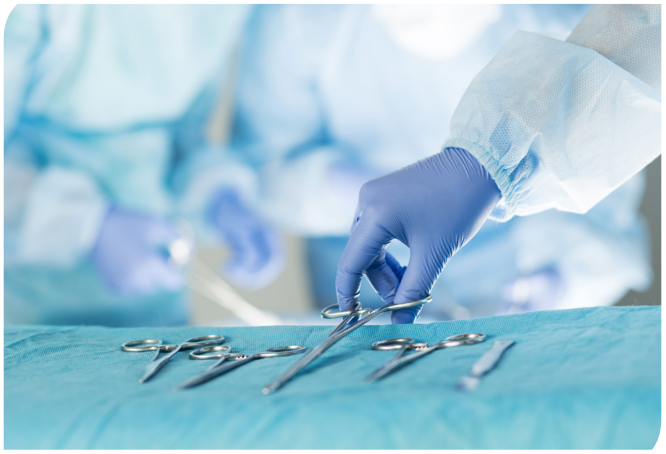
- Gain a complete overview of the biocompatibility requirements in the EU and US to ensure compliance
- Examine important parts within ISO 10933 to ensure your device manages biological risk
- Examine the link between biocompatibility and ISO 14971 risk management
- Examine the Medical Device Regulation (MDR) safety requirements in the context of biocompatibility to maintain compliance
- How to plan and undertake a biological evaluation of a medical device
- Detailed understanding of the chemical characterisation and toxicological evaluation
- Explore material characterisation and learn how to characterise novel materials

Qualification

Certificate of Attendance

Programme Costs & Schedule

Please visit www.IrishMedtechSkillnet.ie for programme costs and upcoming schedule.



Benefits of Attending

At the end of the course, delegates will gain a detailed knowledge of:

- Build your Biological Evaluation Plan and create a strategy to meet current ISO 10993-1 expectations.
- Avoid wasted time in the development process by understanding where your biocompatibility gaps are so that you can address them in a timely manner
- Demonstrate to regulatory agencies that the biological evaluation plan was assembled by those with appropriate expertise
- ”Common pitfalls” – avoid the typical mistakes
- Understand biological evaluations to ensure you can outsource effectively and can interpret results
- Learn to interpret the requirements to identify and determine testing end-points

Programme

Module 1: Introduction to the course and overview of biocompatibility

- What is biocompatibility and why is a biological evaluation needed?
- Examining the ISO 10993 series – biological evaluation
- Examine the impact of the Medical device Regulation (MDR)
- The relation between ISO 10993 and the risk management standard ISO 14971
- Medical device categorization for biological risk assessment
- Medical Device Directive (MDD) safety requirements vs the Medical Device Regulation (MDR) safety requirements
- MDR, FDA and biocompatibility
- Evaluation and testing within a risk management process: Use of ISO 10993-1
- Chemical Characterization and Toxicological Evaluation: Use of ISO 10993-18 & -17

Module 2: Biological evaluation – FAB four

- Biocompatibility testing – Endpoints to be addressed in a biological risk assessment
- GLP requirements
- Lab selection
- FAB FOUR: Cytotoxicity, irritation, sensitisation and acute systemic toxicity
- Endotoxin contamination and material mediated pyrogenicity: US-FDA expectations
- What you should consider in the communication with the test-house

Module 3: Long term toxicity and sample preparation

- Genotoxicity ISO 10993-3 “Tests for genotoxicity, carcinogenicity and reproductive toxicity” & ISO/TR 10993-33 “Guidance on tests to evaluate genotoxicity - Supplement to ISO 10993-3”
- ISO 10993-4: Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
- Sample Preparation ISO 10993-12 “Biological evaluation of medical devices -Part 12: Sample preparation and reference materials”

Module 4: Chemical Characterization and Toxicological Evaluation: Use of ISO 10993-18 & -17

- Physical and Chemical characterisation as part of material qualification and selection
- Summary of the different steps to be addressed for a proper Extractables-Leachables Screening Study
- Illustration of different study designs which may be applied for complex materials consisting of many different parts
- Overview and selection of chemical testing methods for material characterization and the use of results
- Definition of an appropriate Tolerable Exposure (TE)
- Selection of different approaches to address a toxicological assessment
- Pills on the new version of ISO 10993-17 (ISO/FDIS: Final Draft of International Standard)
- Conclusions and next step after a Toxicological Risk Assessment

Irish Medtech Skillnet Programmes

Please visit www.IrishMedtechSkillnet.ie to learn about our transformative, funded training programmes for Medtech and manufacturing companies in Ireland.

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An Roinn Breisoideachais agus Ardoideachais, Taighde, Nuálaíochta agus Eolaíocht
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