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Irish Medtech Skillnet



Biological Evaluation of Medical Devices

Four Sessions Virtual Classroom

Oct. 14, 2020 - Oct. 23, 2020

Speaker

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Introduction

This training course will describe the big-picture concepts 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.

Topics covered

- Introduction to biological evaluation concepts, within the framework of medical devices global regulation
- ISO 10993 standard series: approaching biocom patibility within the whole device risk management process
- Understanding and knowing the device as first crucial step to approach biological evaluation
- Chemical characterization of the materials
- Extractable/Leechable studies as a perfect way to characterize many medical devices
- Toxicological assessment (ISO 10993-17) applica tion in order to evaluate obtained data from chemi cal characterization
- Biocompatibility tests overview:
  - Cytotoxity, irritation, sensitization
  - Acute effects evaluation
  - Long term studies implantation and systemic toxicity studies
  - Genotoxicity
  - The difficult evaluation of devices in contact with blood
- Case study

Benefits in attending

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

- Biological evaluation of medical devices within a Risk Management Process
- Key points of the ISO 10993 series of standards
- How to approach biological evaluation
- The importance of chemical characterization testing for medical devices
- The role of toxicological risk assessment for medical devices
- How to plan and undertake a biological evaluation of a medical device
- Highlights on acceptance criteria of biocompatibility testing by international authorities

Programme

14/10/2020 – Module 1 (9.00 am – 12.45 pm)

- Regulatory framework: The new EU Regulations on medical devices
- EU Medical Device Regulation 2017/745: General Safety Requirements and Biological Evaluation
- Evaluation and testing within a risk management process: Use of ISO 10993-1
- Chemical Characterization and Toxicological Evaluation: Use of ISO 10993-18 & -17

16/10/2020 – Module 2 (9.00 am – 12.45 pm)

- Sample Preparation ISO 10993-12 “Biological evaluation of medical devices -Part 12: Sample preparation and reference materials”
- FAB FOUR: Cytotoxicity, irritation, sensitization and acute systemic toxicity

21/10/2020 – Module 3 (9.00 am – 12.45 pm)

- Endotoxin contamination and material mediated pyrogenicity: US-FDA expectations
- 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

23/10/2020 – Module 4 (9.00 am – 12.45 pm)

- FDA EXPECTATIONS: Use of International Standard ISO 10993-1, “Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process”
- Change management: Impact of changes on biocompatibility
- Case study
- Group excercise and final Q&A