Veranex

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Basic Biocompatibility
Practical Perspective & Regulatory Aspects

TRAINING FACTSHEET


Speakers:
Monica Grekula & Lina Burman

Date: February 20th & 22nd 2024, Online
Duration: 6 hours | 2x 2:00 – 5:00 PM CET
2 x 8:00 – 11:00 AM EST

About the speakers:

Monica Grekula - *ERT (European Registered Toxicologist), MSc Applied Toxicology, MSc Pharma*
Monica has over 25 years of experience in the field of medical devices, mainly within biological evaluation, all phases from a global perspective for class I – class III medical devices, as well as Combination Products. Experience from whole life-cycle risk management, setting up procedures and leading teams and has been involved in different development projects, both within pharma and medical devices.

Lina Burman - *PhD in Polymer Technology with focus on evaluation of migration and degradation behavior of polymeric materials*
Lina has 15 years of experience within the medical device industry, working mainly with biological evaluations and toxicological assessments, of which 10 years with focus on breathing gas pathway related devices as part of the development team. Responsibility of evaluation of class I – class III devices for the EU and US markets. In addition, experience within clinical evaluations, environment related requirements, failure evaluations, chemical characterization, and QMS.

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TRAINING OBJECTIVES:

By attending this training you will develop a basic understanding of biocompatibility-related issues and requirements you can reduce the likelihood of:

- Time-consuming and costly mistakes when choosing materials;
- Having to re-do testing;
- Biocompatibility-related adverse events following material changes;
- Deviations related to material changes at audits; and
- Questions at filing to notified body and authorities.

The course will improve your understanding of biocompatibility to:

- Ensure timely consideration of biocompatibility-related aspects during development;
- Facilitate discussions with those responsible for biological evaluation and test houses; and
- Ease reviewing of biocompatibility-related documentation for regulatory purposes or clinical evaluations.

The course also gives a good introduction to the area if you will be working with biological evaluations and you're new to the field.

TRAINING CONTENT:

Day 1:

- Definition and connection to other processes - risk management, clinical evaluation, quality system process (ISO 14971, ISO 14155, ISO 13485) and Design Development
- ISO 10993-1 general principles and process
- Endpoints of concern and product-specific hazards
- Information needed for biological evaluation, incl. choice of chemical information or chemical analysis
- Overview ISO 10993 remaining standards
- Changes that trigger update of evaluation and case studies
- Group exercise

Day 2:

- Basics to think about in material selection and dealing with suppliers
- Basics to think of when setting up tests with test house
    - Biological testing
    - Chemical characterization

- Key points to be covered due to the EU MDR 2017/745 GSPR
- What notified bodies want to see
- Global aspects

TRAINING FORMAT:

- Presentation with interactive discussions
- Exercises during the training
- End of training assessment (participants will receive a training certificate)

TO WHOM IT IS ADDRESSED:

This course is for beginners and basic needs – Suitable for those of you who need a basic understanding, e.g. working as project managers, R&D engineers, regulatory managers, quality engineers, sustaining engineers, and/or involved in vigilance investigations and clinical evaluations, as well as beginners within biological evaluations.

PRICE:

EUR 620 incl course material and certificate

Registration: https://education-veranex.talentlms.com/
Contact: MDD-training@veranex.com