Tailored training course:
"Biological evaluation of medical devices"

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 biocompatibility 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: what does it means in practice
- Extractable/Leachable studies as a perfect way to characterize many medical devices
- Toxicological assessment (ISO 10993-17) application in order to evaluate obtained data from chemical characterization
- Bridge approach and change management optimization thanks to chemical characterization
- Biocompatibility tests overview:
    - The big 3: cytotoxicity, irritation, sensitization
    - Acute effects evaluation: acute systemic toxicity, pyrogens and endotoxin tests
    - Long term studies implantation and systemic toxicity studies
    - Genotoxicity: the new ISO 10993-3 and ISO 10933-33 approach and requirements
    - The difficult evaluation of devices in contact with blood
- Biocompatibility testing acceptance by international authority: accreditation requirements and philosophical differences
- Case study
- Q & A session

Course outcomes:

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