Biocompatibility of materials and sterilization methods: an introduction
Speaker Lecturer: Alexandre Anesi, Department of Medical and Surgical Sciences for Children & Adults, University Hospital of Modena and Reggio Emilia

June 10-22-29 2021, July 6, 13,14 2021
Hour: 10.00 – 12.00

Online course
The course aims to provide an introduction to the concepts of biocompatibility and the body’s reaction to implants.
For medical devices that directly or indirectly contact patients, biocompatibility testing is required to obtain regulatory approval in most markets. The students will learn principles of biocompatibility, including medical devices, biomaterials, biological systems these devices interact with, host and material responses and biocompatibility testing.
The students are invited to apply knowledge of biological performance concepts to development of preclinical evaluation programs for medical materials and devices, in particular tissue engineered devices that incorporate biological materials and cultured cells.
The need of biomaterial sterility will be underlined, prior to the incorporation of cells or in living tissues. How material sterilization and handling may affect device/material function will be discussed.

Subtopics:
- Biological evaluation process for a medical device
- Categorization (intended use, body location, duration of use)
- Characterizations (materials)
- Need for testing
- In vitro testing
- In vivo testing
- Developing a biological performance testing strategy according to ISO 10993 guidelines
- Applications of ISO 10993-6:2016 Biological evaluation of medical devices Part 6: Tests for local effects after implantation
- Fundamentals of sterilization
- Material sterilization and handling may affect device/material function
- Selection of the most appropriate sterilization procedure, specific to the material used and its intended application

Exam: A written report and/or a narrated ‘presentation’ (individual) and peer review of each other’s presentations (group).
Final discussion (group).