CEISO
TRAINING CENTER

REF. GR06 - INTRA/INTER

MANAGING RISKS

Biological Evaluation of Medical Devices according to EN ISO 10993-1

COURSE DESCRIPTION

To place Medical Devices on the market in Europe, the requirements of Regulation (EU) 2017/745 must be met.

The manufacturer must design and manufacture its devices so as to ensure that, under normal conditions of use and considering their chemical, physical and biological properties, they are suited for their intended use, safe and effective, and do not endanger the clinical condition or safety of patients or the safety or health of users.

DURATION
1 day/7 hours

IN-PERSON

VIRTUAL CLASSROOM

OBJECTIVES

- Become familiar with the requirements and methodology to demonstrate the biocompatibility of the medical devices
- Understand the factors that have an impact on biocompatibility
- Integrate biocompatibility requirements into the design process

TARGET TRAINEES

Medical Device manufacturers, and more particularly:
- R&D
- Regulatory Affairs
- Quality Assurance

PREREQUISITES

- Familiarity with Regulation (EU) 2017/745 is a plus.

TRAINING RESOURCES

- PowerPoint presentation handed out at the end of training
- Case studies
- Experience sharing
- Quizzes

COURSE CONTENT

Participants welcomed and presented/Course objectives/ Presentation of the course content

1. Regulatory framework
   a. The relationship between EN 10993-1 and the GSPR
   b. Design and manufacturing requirements
2. EN ISO 10993-1
   a. Scope
   b. General principles and vocabulary
   c. Tie to the other standards in the ISO 10993 series
   d. Tie to the risk management process
3. Biological evaluation process
   a. The different stages
   b. Medical Device classification
   c. Input data for the biological evaluation
   d. Chemical characterization and bioassays
   e. General understanding of biological risks
4. Summary/Q&A
5. Course evaluation and conclusion

EVALUATION METHODS

Course evaluation quiz
Satisfaction survey
Attendance certificate

This training is assessed based on an evaluation of each individual's acquisition of knowledge via quizzes during and at the end of the program *(success criteria >= 75%).*

Do you have a question? Contact us!
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