

# Safety and Essential Performance Requirements for Medical Electrical Equipment - EN 60601-1

## COURSE DESCRIPTION

To place Medical Devices (MD) on the market in Europe, the requirements of Regulation (EU) 2017/745 must be met. The manufacturer must design and manufacture its medical electrical equipment so as to ensure it is safe and effective, and does not endanger the clinical condition or safety of patients or the safety and health of users. EN 60601-1 sets out the requirements for tests, performance, information to be provided and labeling, and has a major impact on the risk management process.

## DURATION

1 day/7 hours



IN-PERSON



VIRTUAL CLASSROOM

## OBJECTIVES

- Understand the concepts set out in EN 60601-1 and better understand the standard's requirements
- Become familiar with the role, operation and expectations of test laboratories to better manage them

## TARGET TRAINEES

Medical Device (MD) manufacturers, and more particularly:

- R&D team
- Purchasing
- Production and Quality Control
- Quality Manager
- Regulatory Affairs Manager

## PREREQUISITES

- Familiarity with the MD sector

## TRAINING RESOURCES

- PowerPoint presentation handed out at the end of training
- Standard document examples
- Normative references
- Quizzes

## COURSE CONTENT

**Participants welcomed and presented/Presentation of the course objectives and method to check that they are achieved**

1. Identify the main concepts of EN 60601-1
2. Understand the organization and structure of the standards in the 60601-1 and 80601-1 series
3. Understand the requirements regarding electrical safety of Medical Devices (and non-Medical Devices)
4. Understand the Constructional requirements
5. Understand the requirements regarding the mechanical safety of Medical Devices
6. Understand the safety requirements regarding hazards due to unintended or excessive radiation from Medical Devices
7. Understand the requirements regarding temperature resistance and other safety features of Medical Devices
8. Summary/Q&A
9. 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*  $\geq 75\%$ ).



**Do you have a question?** Contact us!

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