

## Seminar IEC 60601-1 Safety of Medical Electrical Equipment

### Learning Content

- Regulatory basics
- IEC 60601-1:2005 + A1 + A2:2020 structure and concepts
- Terms basic safety and essential performance characteristics
- Basics of single fault safety, electrical safety (MOP, MOOP, MOPP), EMC, and IEC 60601-1-2
- Selection of components
- Interaction with risk management according to ISO 14971
- Introduction ME systems
- Requirements for PEMS (software)
- Planned and latest changes and best practices

### Schedule

Day 1

Time	Content
09:00 am - 09:30 am	Introduction and expectations
09:30 am - 10:30 am	Objectives and scope of the standard: interaction with European regulations, scope and definition of ME equipment/systems, structure and structural elements of the standard
15 min break	
10:45 am - 12:30 pm	Definitions of terms: Basic safety, essential performance characteristics + exercise
60 min lunch break	
01:30 pm - 02:30 pm	Interaction with risk management according to ISO 14971 + exercise
02:30 pm - 03:00 pm	Terminology: Normal condition, single fault safety, abnormal condition
15 min break	
03:15 pm - 03:45 pm	Exercise on terminology
03:45 pm - 04:45 pm	Interpretation sheet IEC 60601-1:ISH1:2021, operational life, dependability and critical components
04:45 pm - 05:00 pm	Summary, questions, discussion

## Day 2

Time	Content
09:00 am - 09:30 am	Repetition from day 1
09:30 am - 10:00 am	Operational life, dependability and critical components
10:00 am - 10:30 am	Basics of electrical safety
15 min break	
10:45 am - 11:30 am	Basics of electrical safety + exercise: isolation diagram
11:30 am - 12:00 pm	Basics EMC and IEC 60601-1-2 (Ed. 4)
60 min lunch break	
01:00 pm - 02:30 pm	Basics ME systems + exercise
15 min break	
02:45 pm - 03:15 pm	Requirements for PEMS, PESS
03:15 pm - 03:30 pm	Optional: Outlook 4th Edition and AMD2
03:30 pm - 04:15 pm	Learning check
04:15 pm - 04:30 pm	Summary, questions, discussion, closing