

Learn the basics of IEC 60601-1 with working examples, team exercises and our industry knowledge and experience. Gain a clear understanding of the safety standard in the medical device sector with an insight into methodologies and techniques as well as the terms and definitions to enable you to successfully pass any regulatory approvals.

Duration: 1 day

Language: English or German

Course Content

- › Risk management & relation to ISO 14971
- › Device classification
- › Identification, marking and documents
- › IEC 60601-1 relation to collateral & particular standards
- › Protection against ELECTRICAL HAZARDS
- › Protection against MECHANICAL HAZARDS
- › Protection against other types of HAZARD
- › Programmable electrical medical systems (PEMS) and the relation to functional safety, IEC 62304 and cybersecurity
- › ME SYSTEMS considerations
- › Electromagnetic compatibility (EMC)

Who Should Attend?

Product Safety Engineers, Compliance Engineers, Product Designers, Regulatory Approval staff, Production Support Engineers, Quality Assurance staff

Prerequisites

This course is suitable for delegates with no prior knowledge of IEC 60601-1 or can be customised for a more experienced audience.

Training Schedule

Training typically runs for 8 hours each day, including a one hour lunch break and two shorter breaks in the morning and afternoon. This can be adapted as required to meet specific business requirements.

Price: £500 per person per day for a minimum of 2 and up to 7 participants. Thereafter a fixed rate will be charged for the training session.



To Book:

For a convenient and cost effective training solution, we can work with your organisation to develop bespoke training to meet your exact requirements.

To book this course or discuss customised training, please email us at info@lorit-consultancy.com or call us on +44 7708 360023.

www.lorit-consultancy.com