IEC 60601 FUNDAMENTALS & EMC TRAINING

IEC 60601 & EMC COURSE

Learn the fundamentals of IEC 60601 with practical examples, team exercises, and insights from industry experience. Gain a clear understanding of safety requirements for medical electrical devices, including key concepts, terminology, and methodologies to support regulatory approval.

This will be followed by a focused introduction to electro-magnetic compatibility (EMC). We will cover regulatory frameworks, applicable standards, and manufacturer responsibilities. The course explores EMC testing to IEC 60601-1-2, risk assessment, and practical design considerations, enabling participants to plan for compliance, avoid common issues, and work effectively with test laboratories.

DURATION: 2 Days

LOCATION: Cambridge UK, venue TBC

TARGET AUDIENCE

Product safety engineers, compliance engineers, product designers, regulatory approval staff, production support engineers, quality assurance staff

FURTHER INFORMATION

Interactive expert-led training. The duration of the training comprises two days, 8 hours / day (incl. a 30-min lunch break and 2 shorter breaks). On request we grant a discount for group bookings.

TRAINERS:

Alastair Walker, Lorit Consultancy
Engineering consultant & 60601 Expert

James Pawson, Think EMC & Unit 3 Compliance
The EMC Problem Solver

COURSE CONTENT

DAY 1 - IEC 60601 Fundamentals - Medical Electrical Equipment Safety

- Risk management & relation to ISO 14971
- Definition of ESSENTIAL PERFORMANCE and BASIC SAFETY
- Device classification
- Identification, marking and documents
- IEC 60601 relation to collateral & particular standards
- Protection against ELECTRICAL HAZARDS
- Protection against MECHANICAL HAZARDS
- Protection against other types of HAZARDS
- Programmable electrical medical systems (PEMS) and the relation to functional safety, IEC 62304 and cybersecurity
- Overview of collateral and particular standards
- ME SYSTEMS considerations
- Future of IEC 60601: Insights into 4th Edition

We are happy to work with your organisation to develop customised and cost effective training.

PLEASE CONTACT US FOR YOUR BOOKING OR ENQUIRY:

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+44 7708 360023

hello@thinkemc.co.uk
+44(0)7811 139957

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COURSE CONTENT

DAY 2 - Electro-Magnetic Compatibility

WHY EMC? Introduction

- Medical Devices Regulations
- EMC Directive, Radio Equipment Directive
- Manufacturer responsibilities
- Technical documentation requirements
- Series production control and changes to equipment

EMC STANDARDS

- Introduction to EN 60601-1-2
- EMC Specification for Medical Devices
- Environments
- Integrating radio equipment and effect on standards

PLANNING FOR EMC TESTING

- Scheduling testing
- EMC risk assessment
- How to plan for testing?
- Software, hardware, personnel requirements
- Working with a test laboratory
- The importance of pre-compliance

EMC TESTS

- Emissions and immunity
- EMC test standards
- What tests are carried out?
- Specific EMC hazards for medical devices
- RF Exposure

EMC DESIGN CONSIDERATIONS

- Common problems and how to avoid them
- System planning, PCB layout considerations
- Using 3rd party components
- Radiated emissions, conducted emissions
- Cable shielding
- ESD
- Galvanic isolation
- Analogue sensing
- Proximity to wireless devices - high E-field immunity testing
- What to do in the event of problems

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