Software requirements according to IEC 60601-1 clause 14 3rd Ed. and IEC 62304

Course Description
During the course the requirements in the IEC 60601-1 and the IEC 62304 will be discussed and explained, to provide a detailed understanding of the software safety compliance process.

Gain insight in the characterization of the software requirements aspects of product, risk assessment regard to software verification and validation aspects, determination of applicable product specification and test requirements and learn how to set up the final reporting and Technical Report Forms.

Learning Objectives
On completion of the training, participants will be able to:

- Understand the software requirement terms and techniques
- Understand the requirements of the applicable (collateral) standards for the product development process
- Understand how to proved the software verification and validation of a medical device
- Understand the requirements for risk assessment and software safety
- Understand the required design and technical documentation
- Determine the applicable analysis and tests
- Cases to perform a risk analysis and software safety tests
- Establish the design and technical documentation records
- Questions & Answers
- Evaluation of the course and Closing

Who should attend
- Quality Managers
- Anyone responsible for the technical design and compliance of medical software systems

The number of participants is maximized to twelve to provide a stimulating and practical working environment.

Level
There is no prerequisite for this course; a basic knowledge of basic safety and essential performance of medical electrical equipment is an advantage

Duration
1 day

Training material
Course notes are provided on a USB stick.