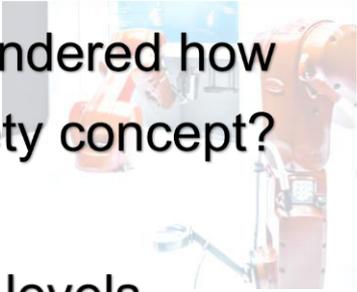


DE0401 Medical Device Development

Functional Safety for Medical Device Engineers



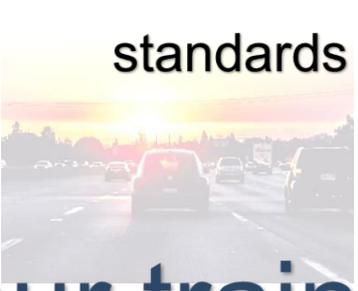
Have you ever asked yourself how to develop a medical device complying with functional safety standards efficiently?



Have you ever wondered how to setup a safety concept?



Have you ever thought about safety integrity levels for medical devices?



Do you know how medical regulations and standards and traditional functional safety standards such as IEC 61508 interact?



Join our training and learn more about **Functional Safety for Medical Device Development**

Agenda and Content

- ◆ Introduction to Functional Safety

- ◆ **Recap** - Regulatory Basics and Legal Aspects for Medical Devices
 - Standards, Regulations and their Interactions
 - Device and Safety Classification
 - Interaction of medical requirements with IEC 61508

- ◆ Essential Performance and Basic Safety
- ◆ Single Fault Safe Systems - Single Fault Conditions

- ◆ Key Techniques to handle Functional Safety in Medical Devices
 - Safety Lifecycle (System-, HW-, SW-Level)
 - Requirements Engineering
 - Architecture, Design and Safety Design Patterns
 - HW-SW-Interface
 - Verification and Validation
 - Safety Analyses
 - Supporting Processes

- ◆ Impact of Artificial Intelligence and Machine Learning to Functional Safety

Who should attend?

Engineers working in medical device development, who want to learn about functional safety, such as:

- ◆ Risk Managers, Safety Managers, Project Managers
- ◆ Development Engineers (System, Hardware and Software)

Basic experience in medical device development is beneficial.

Duration: 1 day

Language: English or German in agreement with the participants.

The training material will be in English.

Location: exida.com GmbH Office
Prof.-Messerschmitt-Straße 1
D-85579 Neubiberg / Germany

On-site or online trainings are also possible on customer request.

Certificate: Each participant gets a confirmation of attendance also listing all the covered topics

For more information, please contact:

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