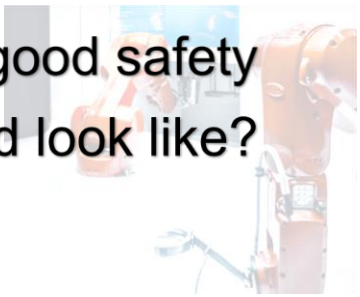
exida

www.exida.eu

DE0401 Functional Safety for Medical Device Development

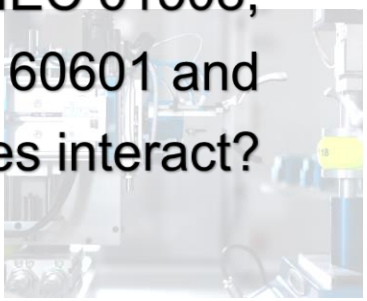
Have you ever asked yourself how to develop a medical device complying with functional safety standards efficiently?



Have you ever wondered how good safety requirements should look like?

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

Do you know how regulations and standards, such as Medical Device Regulation, IEC 61508, IEC 62304, ISO 14971, IEC 60601 and FDA Guidelines interact?



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

exida excellence in *Dependable Automation*

Agenda and Content

- Introduction to Functional Safety
- Regulatory Basics and Legal Aspects
  - Standards, Regulations and their Interactions, such as:
    - Medical Device Regulation (MDR)
    - IEC 61508
    - ISO 14971
    - IEC 60601
    - IEC 62304
    - FDA Regulations and Guidelines
  - Device and Safety Classification
- Essential Performance and Basic Safety
- Single Fault Safe Systems - Single Fault Conditions
- Key Techniques to handle Functional Safety
  - Safety Lifecycle (System-, HW-, SW-Level)
  - Risk Management
  - Requirements Engineering
  - Architecture, Design and Safety Design Patterns
  - HW-SW-Interface
  - Verification and Validation
  - Safety Analyses
- Impact of Artificial Intelligence and Machine Learning to Functional Safety
- Supporting Processes

Who should attend?

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

Duration: 1 day

Language: Englich 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:

Kerstin Tietel
+49 89 44118232
kerstin.tietel@exida.com