

Medical Device Development (DE0401)

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Functional Safety for Medical Device Development

Who should attend

- Safety Managers
- Development Engineers (System, Hardware and Software)
- Product Managers
- Project Leaders of safety related development projects
- Process Managers
- Quality Managers

Duration: 2 days

Language: German or English, training material will be in English.

Location: exida.com GmbH office

Prof.-Messerschmitt-
Straße 1
D-85579 Neuberg /
Germany

or **ONLINE**

Course topics:

- Introduction to Functional Safety
 - Regulatory Basics and Legal Aspects
 - Interaction of Standards and Regulations, such as:
 - IEC 61508
 - ISO 14971
 - IEC 60601
 - IEC 62304
 - Medical Device Regulation (MDR)
 - FDA Regulations and Guidelines
 - Device and Safety Classification
- Impact of Faults to Systems
- Single Fault Conditions
- Key Techniques to handle Functional Safety
 - Safety Management
 - Requirements Engineering
 - Architecture and Design
 - HW-SW-Interface
 - Verification and Validation Techniques
 - Safety Analyses
- Supporting Processes
- Workshop: Guided development of selected tasks for an example project

Brochure



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Scheduled courses -

[Register here:](#)