

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

# DE0401 Functional Safety for Medical Device Development

This training will support to lay a basis for the **understanding of functional safety** with regard to Medical Device Development.

It will provide **guidance and suggestions** for critical topics such as risk management, safety related requirements, architecture and design or verification & validation.

The learning success will be supported by practical examples and exercises.

The training will also include the **interpretation and application** of standards such as IEC 61508, IEC 62304, Medical Device Regulation, ISO 14971, IEC 60601 and FDA Guidelines with regard to medical device development.

To apply what you have learned, a half day **workshop** will give some hands-on experience (tool based or/and with paper and pen) for an example project which can be adopted to your needs.

## General approach:

- The exida approach is to explain **how** the requirements of various standards and regulations can be fulfilled, and not only to show and introduce their requirements.
- The standards and guidelines define a route, typical **solutions** are exemplified using e.g. tools delivered or recommended by exida.com (SafetyCaseDB, FMEDA-Tools, Enterprise Architect and other).

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## 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 (1.5 days training + 0.5 day workshop)

### Language:

Can be chosen between German or English, training material will be in English

### Location:

exida.com GmbH office  
Prof.-Messerschmitt-Straße 1  
D-85579 Neubiberg / Germany

### Certificate:

Each participant gets a letter of attendance.

For more information, please contact:

Kerstin Tietel

☎ +49 89 44118232



[kerstin.tietel@exida.com](mailto:kerstin.tietel@exida.com)

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## Interactive Workshop - 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