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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).

DE0401 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 (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:

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DE0401 Functional Safety for Medical Device Development

Agenda

- Introduction to Functional Safety
  - Regulatory Basics and Legal Aspects
  - Distinction between functional safety and electrical safety
  - Interaction of Standards and Regulations, such as:
    - IEC 61508
    - IEC 62304
    - Medical Device Regulation (MDR)
    - FDA Regulations
    - ISO 14971
    - IEC 60601
- Impact of Faults to Systems
- Fundamental Concepts
  - Development Lifecycle Models
  - Hazard and Risk Analysis and Risk Management
  - (Device) Classification in accordance to MDR, Safety Integrity Levels (IEC 61508), Software Safety Classification (IEC 62304), FDA Level of Concerns
  - Safety related requirements
- Key Techniques to handle Functional Safety on System, HW and SW Level
  - Architecture and Design Patterns
  - Requirements Engineering
  - Safety Analysis methods, such as FME(D)A, FTA, DFA
  - Verification and Validation techniques
- Model based development
- Impact of development and test tools on functional safety
- Supporting Processes
  - Change Management
  - Configuration Management
- Workshop: Guided development of selected tasks for an example project