Functional Safety for Medical Device Development (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

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

Course topics:

- 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

Brochure

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Scheduled courses