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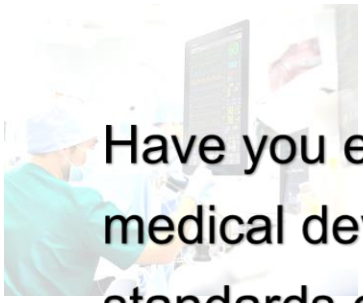
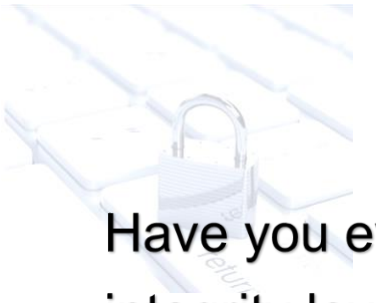
DE0402 Medical Device Development

Medical Device Development for Safety Engineers

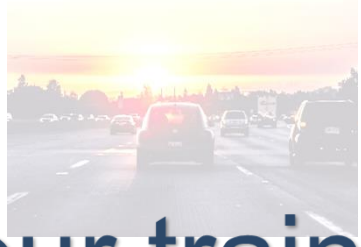


Have you ever asked yourself how to develop a medical device complying with functional safety standards efficiently?

Do you know which regulations and standards need to be addressed for safety related medical devices?



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



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

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Agenda and Content

- ***Recap*** - Introduction to Functional Safety

- Regulatory Basics and Legal Aspects for Medical Devices
  - Standards, Regulations and their Interactions, such as:
    - Medical Device Regulation (MDR)
    - ISO 14971
    - IEC 60601
    - IEC 62304
    - IEC 61508
    - FDA Regulations and Guidelines
  - Device and Safety Classification

- Essential Performance and Basic Safety
- Single Fault Safe Systems - Single Fault Conditions

- Creating a safety argument based on key techniques to handle Functional Safety in Medical Devices
  - Risk Management Lifecycle
  - Architecture, Design and Safety Design Patterns
  - Verification and Validation
  - Safety Analyses

- Impact of Artificial Intelligence and Machine Learning to Functional Safety

Who should attend?

Safety engineers, who want to learn more about safety related medical device development, such as:

- Safety Managers and Project Managers
- Development and Safety Engineers (System, HW and SW)

Basic experience in functional safety is beneficial.

Duration:	1 day
Language:	English 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:

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