

## SOFTWARE ENGINEER - MEDICAL AND HEALTH SERVICES

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Company: TÜV SÜD

Location: Thailand

Category: other-general

### **Aufgaben**

The expert is responsible for assessing the safety and performance of medical device in aspects of software to ensure that manufacturers comply with relevant regulations and standards.

### **Key Responsibilities:**

Safeguard the next generation of new medical products from software-related risks that can potentially harm patients and users.

Be the fore-front expert in code quality and development best practices.

Conducting thorough reviews of code for quality, correctness, efficiency, and adherence to regulatory requirements and coding standards.

Identify performance and safety issues, logical errors, potential security vulnerabilities, and deviations from coding standards.

Provide constructive feedback to manufacturers on compliance issues and deviation from best practices.

Ensure software development process aligns with established compliance frameworks and guidelines.

Deep understanding of technical documentation requirements for software-enabled medical devices, including but not limited to software specifications, design and architecture documents, risk management files, and software validation plans.

Evaluating risk management files for software-enabled medical devices, including risk analysis, risk evaluation, and risk control measures to ensure appropriate identification,

assessment, and mitigation of risks throughout the product lifecycle.

## Qualifikationen

### Key Requirements:

Bachelor's or Master's degree in computer science, Software Engineering, Biomedical Engineering, or a related field

At least 2 years of experience in software development (this includes the time for master's & PhD Thesis) with proficiency in programming languages. For example: Python, Java, C++, JavaScript, NodeJS.

Preferably with 4 years exposure in the medical/ healthcare industry with knowledge on medical standards and regulations for example, ISO13485, EU Medical Device Regulation (MDR)

Strong communication skills to communicate effectively with customers and internal teams, and articulate assessment findings clearly and professionally.

Strong technical writing abilities to provide clear and concise feedback on the technical documentation and communicate assessment findings effectively.

The ability to work independently and as part of a team and under pressure to meet deadlines and maintain confidentiality.

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