

## Quality Medical Software Engineer (m/f/d)

At midge medical, we're reimagining the way healthcare systems work. You'll have the chance to be part of that change within a diverse and growing team. We are creating the exciting opportunity for you to leave your footprint.

midge medical is developing diagnostic devices based on blood and other body fluids that are so easy to operate that they can be used by consumers as well as by health care professionals. The complete digitization of the testing procedure is at the core of our vision. We believe testing should be available, accessible, and affordable for all. With our aim for ubiquitous testing, we will create a healthier world, reduce infections, and take the pressure off public medical resources.

You can contribute to our team as Quality Engineer and be at the center of all QMS and Quality Assurance activities.

### As a Quality Medical Software Engineer, you will:

Lead and improve the development of the midge medical Quality Manual, Quality Management System, Quality Management Policy, Quality Goals, and applicable laws and regulations. You work closely with your peers and the technology team to build and fulfill the regulatory requirements and deliver all Quality & Compliance certifications as ISO 13485 and training, with a focus on Quality Management for our software platforms. In this role, you will need to:

- Establish medical software certification processes (IVDR, MDR)
- Support process specification and establishment within the company as well as Design Transfer activities across company
- Conduct internal audits
- Act as internal consultant to functional departments, e.g. Purchasing, Marketing, Production Engineering, and support their quality activities
- Actively contribute to designing and/or advancing an automated testing framework for verification and validation of product hardware & software epics, features and user stories for acceptance, functional, regression & performance testing.
- Use test automation techniques that fit the problem space, contribute to automation reviews.
- Support production, product tracing and non-conformity reports of own or 3<sup>rd</sup> party suppliers.
- Demonstrate advanced skills in integrating project testing with continuous-integration processes.
- Identify and manage issues, risks and dependencies, escalating where appropriate
- Use your understanding of Agile software development methods and drive the advancement of test automation within the organization's development methodology.
- Work closely with peers and engage with a fast-paced technical design and development team to deliver tasks to meet product release goals.

**Required qualifications/ assets are**

- Bachelor's degree or above in computer science, engineering, healthcare, physics or related fields
- 5+ years experience in working in a regulated environment (medical, aircraft, information security, military etc.)
- Experience with IVDD/IVDR/MDR certification process and regulation
- Experience introducing and/or working with ISO 13485
- Strong problem-solving abilities and capable of articulating specific technical topics or assignments
- Able to work under minimal supervision
- Excellent communication skills and the ability to interface with peers, development staff and senior leadership
- Skilled in providing oversight and guidance to team members
- German and English language skills (C1 or higher)

**Preferred qualifications**

- Deep knowledge of automated testing frameworks and languages
- Product development and testing, with significant automation experience.
- Experience in end-to-end system testing and automation for small to medium complexity products involving hardware and software.
- Knowledge of automated software build and testing platforms
- Experience working as part of teams following Agile Scrum methodology
- Jira, Confluence, SAP S4/Hana
- Knowledge on IEC 62304 and/or IEC 82304

**Place of work**

Berlin, Germany

**When can you start?**

As soon as we have agreed that we are a match!

Berlin, September 2021