Hardware Development Quality Engineer (m/f/d)

Setting
At midge, we're reimagining the way healthcare systems work. You'll have the chance to be part of that change within a diverse and fast-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 professionals. The complete digitization of the testing procedure is at the core of our vision. You can contribute to our team as Hardware Development Quality Engineer and be at the center of all hardware development activities.
As Hardware Development Quality Engineer, you will
be responsible for representing quality in product development projects and development partner management. Fully integrated to our hardware development team you will have the supervision of our technical documentation.

- Be responsible for providing quality expertise as well as creating, reviewing, and approving quality documentation to ensure compliance with internal procedures and regulatory requirements for medical devices.

- Track fall back issues in your area and work with operations/quality on reduction effort

- Manage quality engineering process and use your prior experience in partner management and quality engineering to maintain key processes, while adhering to regulatory requirements

- Ensure development quality audit processes is implemented effectively

- Create and maintain operational documentation for your area

- Cross-train other employees on duties

- Be responsible for providing adequate level of oversight with development partners and external development quality documentation, as well as ensuring for other comparable areas (like procurement, design transfer and manufacturing) processes are meeting business goals and quality standards.

- Develop relationships and interfaces with development partners to maintain positive performance and hold development partners accountable when business or quality needs are not met.

- Perform minor trouble shooting on non-compliances

Must-Have Assets are

- Attention to detail
- Bachelor in scientific discipline (Engineering, Molecular Biology or Biochemistry preferred)
- 4+ years' experience in a development quality engineering and/or design / manufacturing role
- Knowledge of applicable EU (ISO 13485) quality system requirements
- Motivated person with a history of developing joint cross-functional solutions
- You have excellent written and spoken English and German language skills

Preferred

- Strong data collection and exploration skills
- You already worked with CAD
- You know how to create testing protocols
- Auditor experience per ISO 13485 and/or FDA Quality System Inspection Technique audits is considered as an asset
- Working freely, with excellent stakeholder management and organizational skills
- You already worked as part of teams following Agile Scrum methodology
- Possibly Blackbelt certification or Senior Lean experience
- You already worked on implementing a compliant development documentation
- You already worked with ERP software applications like SAP S4/Hana, Jira
- Travel required: +/- 20%

Place of work
Berlin, Germany

When can you start?
As soon as we have agreed that we are a match!