Software Quality Assurance Specialist

Copenhagen Area, Denmark

Are you excited by cutting edge technology in the artificial intelligence and software medical device space? Are you passionate about impacting the “Quality culture”? Do you have experience with software and medical devices?

We have just the opportunity for you!

This well-established Danish company is a global leader in AI-driven technology and is paving the way in precision pathology software. They have a hard-working and ambitious work ethic but also value the importance of a proper work-life balance.

Even with a multicultural team spread across the globe, they still have a close-knit, family culture where you will be a part of their growth story and help to shape the organisation’s quality culture. No political red-tape here!

Get in touch at kristina@elemed.eu

The role

Based in their headquarters in Copenhagen, a key focus in this position will be to further develop, maintain and improve the Quality Management System, working together with the Senior Quality Assurance Manager and the Chief Clinical And Regulatory Officer.

This is a great opportunity to join a mature organisation where you can still make an impact on business processes and embed a culture of quality across the organisation. You will be hands-on with quality activities such as shaping the QMS, ensuring compliance with the relevant requirements and embedding agile methodologies in the company.

This is a rapidly growing and changing role where you will influence not on the quality department but the entire company and the internal processes.

As Software Quality Assurance you will be one step away from the Chief Regulatory and Clinical Officer) who is collaborating with the FDA to create the guidelines for AI medical device registration in the US. You will be at the forefront of defining the general principles for artificial intelligence and bringing cutting edge technology to market.

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The role

As Software Quality Assurance Specialist you will:

- Maintain and ensure the effectiveness of the Quality Management System to meet the company's needs
- Work cross-functionally and contribute to ensure the design, development, and maintenance complying to standards ISO 62304, ISO 13485 and IVDR regulations
- Participate in vigilance, complaint handling and CAPA processes and support the leadership in reporting to the competent authorities and Field Corrective Actions if required
- Ensure that the design and development process, as well as the total lifecycle, is executed according to the relevant standards and regulations
- Support changes to the QMS to create more efficient and lean processes and implement them across the business
- Help generate, review and edit SOPs and other applicable documentation within the QMS responsibility
- Verify of DHF, DHR and DMR
- Test and release intermediate, final and manufactured product
- Inspect and release incoming goods
- Analyse and monitor trends to verify the effectiveness of company processes
- Host internal audits, supplied audits and external audits

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Why this company?

- Bring cutting edge A.I. technology to market under the IVDR
- Danish company with Danish founders that are still within the company giving the company culture a family feeling and value having a work-life balance
- Multinational team spread across the world
- Working closely with senior leadership collaborating with the FDA to create the guidelines for AI medical device registration in the US
- Be at the forefront of defining the general principles for artificial intelligence
- Opportunity to be part of the growth story and shape the organisation's quality culture

The requirements

- Minimum 3 years of experience in software and the medical device industry or in-vitro diagnostics industry
- Hands-on experience with ISO 13485 and IEC 62304
- Fluent written and spoken English OR Danish
- Flexible, problem-solving and pragmatic mindset

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Interested in further CONVERSATION?

Please send your CV to kristina@elemed.eu to arrange a confidential career discussion.