SENIOR SOFTWARE QUALITY ENGINEER

Copenhagen, Denmark

THE COMPANY

Are you excited by cutting edge technology in the artificial intelligence and software medical device space? Are you passionate about collaborating with development teams?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!

THE ROLE

Based in their headquarters in Copenhagen, a key focus in this position will be to support the implementation of a new, agile quality culture cross-functionally working together with development teams. You will be hands-on with quality activities such as updating DHFs, ensuring compliance with the relevant requirements and developing a new way of working in support of the R&D team. This is a rapidly growing and changing role where you will influence not only the FDA, but also the quality team and the internal processes.

ACTIVITIES ASSOCIATED WITH THIS ROLE

- Work cross-functionally with R&D to ensure requirements, V&V tests, traceability and other related reports are compliant with the relevant regulations and standards all around the world
- Design, implement and maintain a new traceability processes and a new traceability matrix
- Advise and support engineers and the R&D team on regulatory compliance requirements
- Interpret quality requirements for the development of software as outlined in the relevant international standards
- Write, in collaboration with the development team, design & development plans, design control plans, risk management plans

As senior software quality engineer you will report directly to 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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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

REQUIREMENTS FOR THIS ROLE

- Minimum 3 years of experience in software quality engineering in 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

If you think you can bring any of the above to Elemed we would LOVE to hear from you!

Send your CV to **hello@elemed.eu** for a confidential career discussion.

Good Luck!