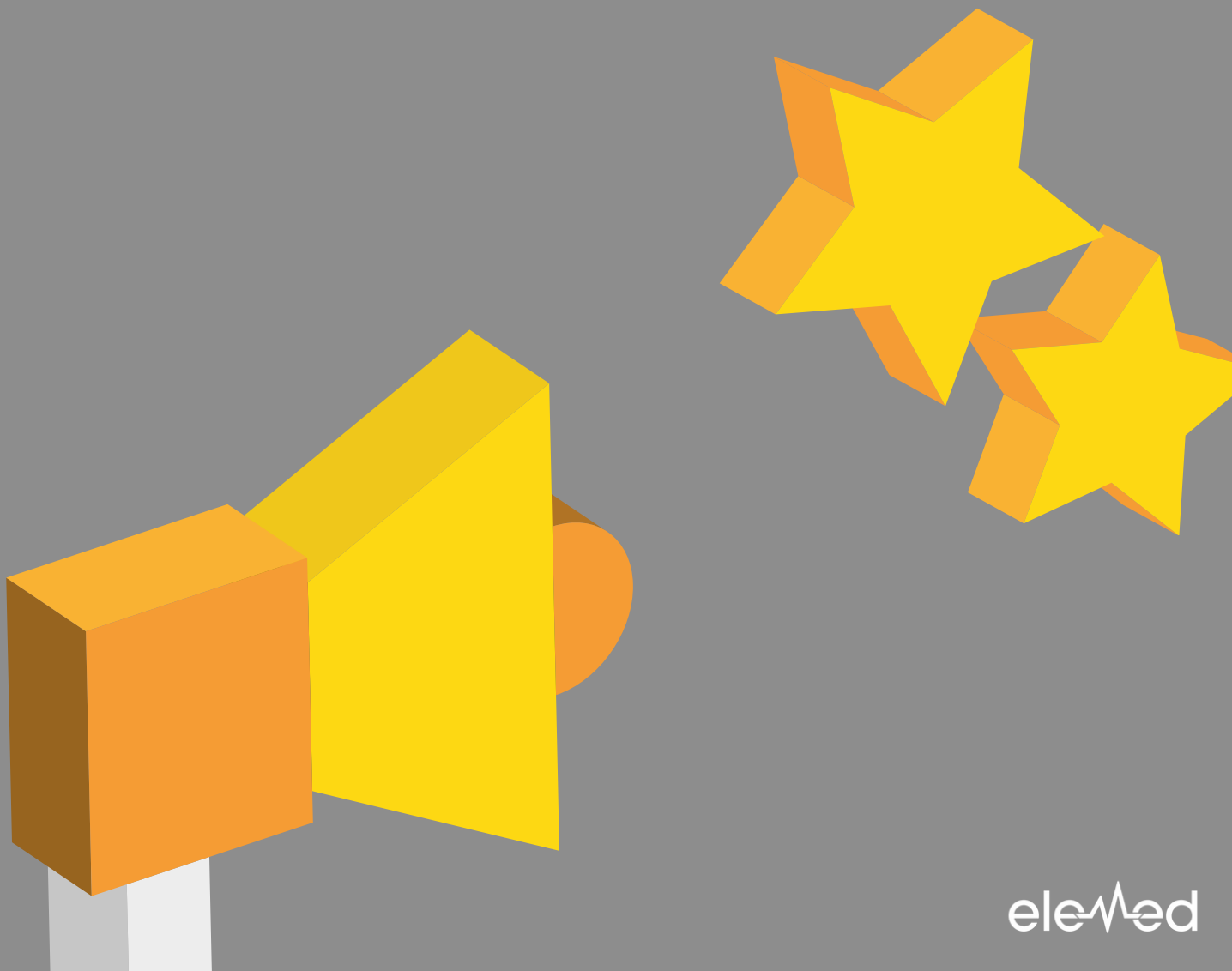
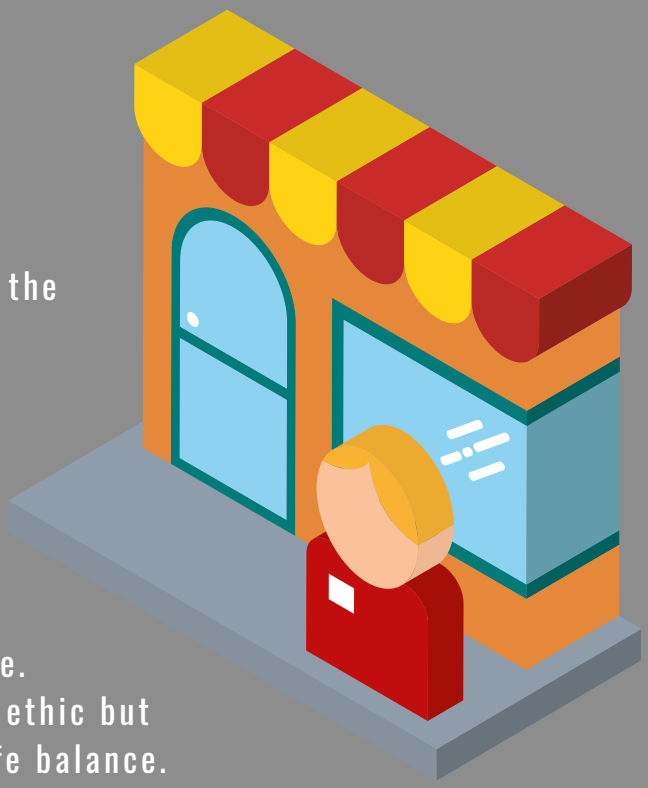
SENIOR QUALITY MANAGER

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!

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 ROLE

Based in their headquarters in Copenhagen, a key focus in this position will be to develop, maintain and improve the Quality Management System working together with key stakeholders and the Chief Clinical And Regulatory Officer. You will be hands-on with quality assurance and quality system activities, ensuring compliance with the relevant requirements and developing new and efficient ways of working in the quality department. This is a great opportunity to step up into a leadership function, leading a team of 2, and further build the quality team for the company.

ACTIVITIES ASSOCIATED WITH THIS ROLE

- Be responsible for maintaining and ensuring the effectiveness of the Quality Management System to meet the company's needs
- Be responsible for 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
- Lead training across the company to ensure the QMS is effective and quality is adopted as a core culture of the company
- Be responsible to generate, review and edit SOPs, and other applicable documentation within the QMS responsibility
- Undertake internal audits and take responsibility for the communication between the company and critical partners relating to quality topics
- Lead, train and develop the quality team

As Quality Assurance Manager 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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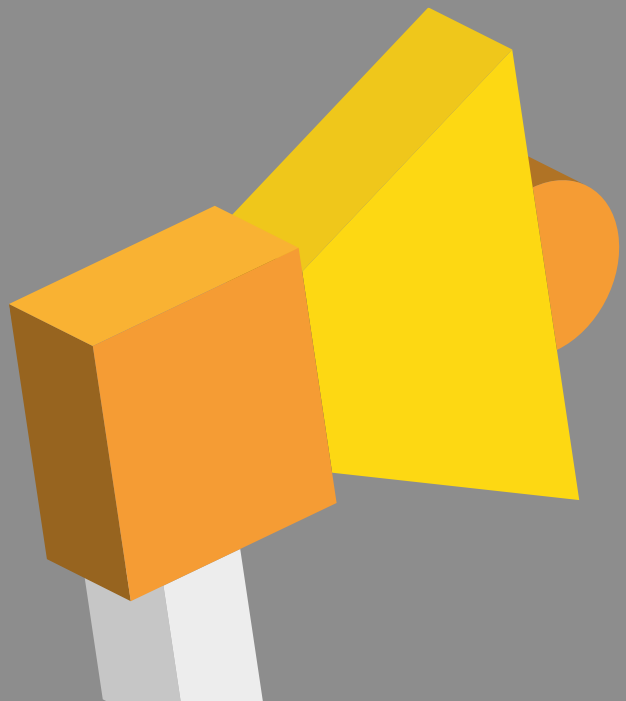
REQUIREMENTS

- 4+ years of experience in QA OR QMS in the medical device industry or in-vitro diagnostics industry
- Hands-on experience with ISO 13485
- Fluent written and spoken English
- Flexible, problem-solving and pragmatic mindset

INTERESTED TO EXPLORE THIS FURTHER?



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