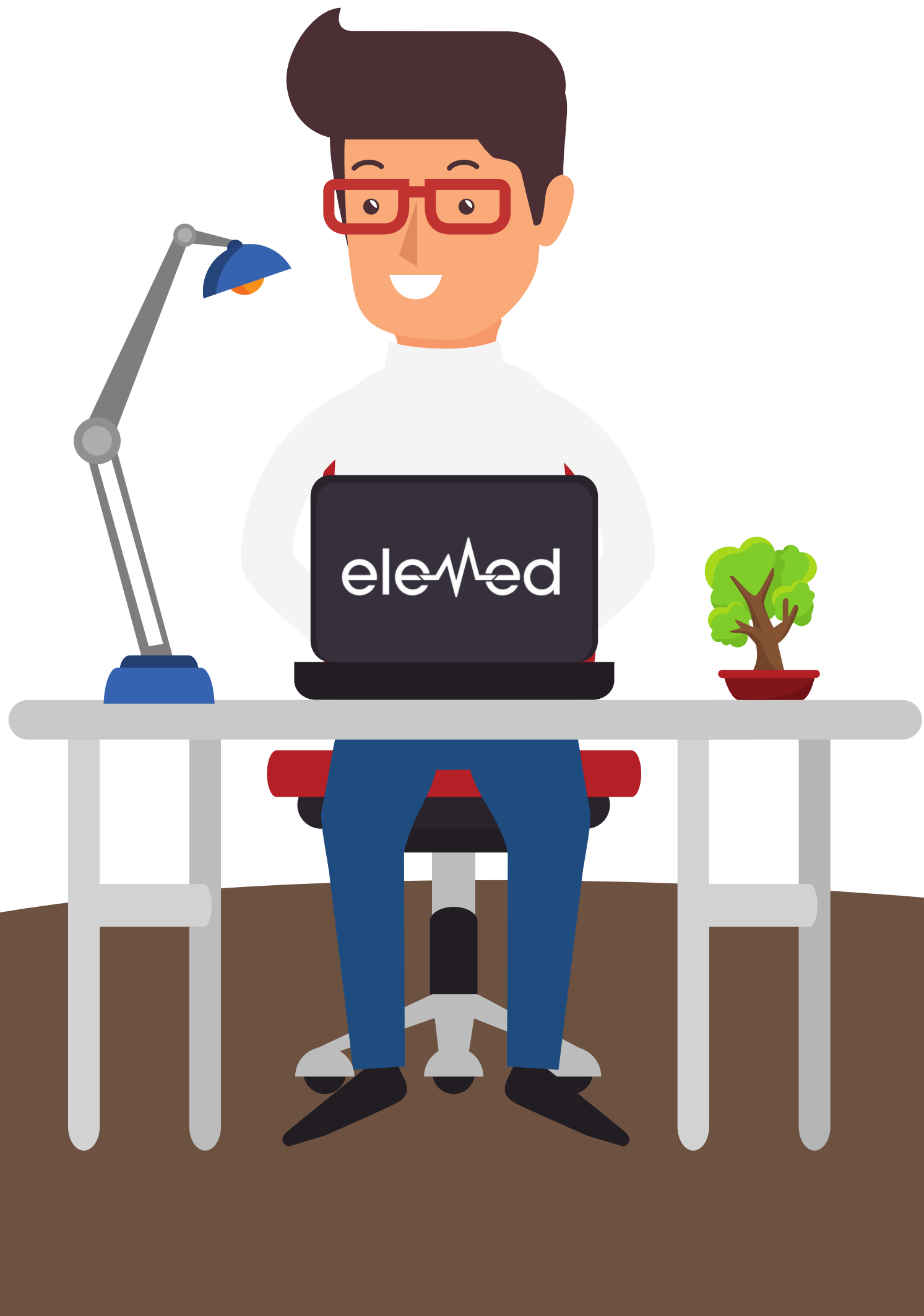
# CLINICAL *manager* AFFAIRS

## HOME-BASED IN EUROPE



# 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? Have you got experience in designing /managing clinical studies?

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

You will have the opportunity to step into a brand new position as Clinical Affairs Manager, no old shoes to fill here, and really shape not just your position but also the direction of the clinical department. Reporting to the Chief Clinical And Regulatory Officer, you become their "right-hand person" in all clinical matters. From designing to implementing to managing; you will lead all phases of the clinical study. If you like thinking strategically and want to continue being "hands-on" this is for you.

As Clinical Affairs Manager, you will be providing a leading role in a variety of clinical study activities such as study strategy, study design and study execution for IVDs and SaMDs. You will have to think outside the box and have a flexible mindset in your approach to studies that are outside of Europe such as US or Japan to bridge the gaps.

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# THE ACTIVITIES

- Supervise, design and support the management of clinical studies globally
- Develop and review documents, presentations and processes specific to the study and create study reports for the clinical parts of regulatory submissions
- Coordinate cross-functional teams throughout clinical studies including quality and regulatory affairs and work closely with the CCRO and stakeholders to ensure alignment and compliance to the company's goals and necessary regulations
- Develop and execute clinical strategy for the company for various projects as they arise
- Set up Clinical Development Plans in alignment with the business strategy and translate business objectives into clinical requirements for clinical trials
- Define and adhere to clear timelines and budgets with the appropriate planning
- Write clinical study protocols for Pre-CE, CE mark and PMCF studies
- Collaborate with cross-functional teams to ensure compliance with internal SOPs, rules and regulations including GCP guidelines
- Ensure clinical trial and study data is of high quality and compliant with the relevant standards for regulatory submission, claim support and health economics
- Support the regulatory affairs team in building the registration dossier with respect to analysis and reporting of results
- Build and maintain key relationships with competent authorities on a local and international level and regulatory agencies such as FDA/SFDA as the company representative. Prepare responses to Clinical Trial questions raised by regulatory agencies

As Clinical Affairs 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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# 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

- 4+ years of experience in clinical studies in the medical device industry or in-vitro diagnostics industry
- Fluent written and spoken English

# INTERESTED IN THIS *position?*

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