# REGULATORY AFFAIRS LEADER

## COPENHAGEN AREA, DENMARK (POSSIBILITY TO BE BASED FROM HOME)

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elemed

# The company

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. If you are interested in gaining experience in medical software and artificial intelligence, the future of MedTech, this could be just the opportunity for you!

A multicultural team spread across the globe, close-knit, family culture where you will be a part of the growth story and no political red-tape are just a few of the things that you can expect when joining this company!

# The role

Based in their headquarters just outside of Copenhagen, you will be the “right-hand person” to 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, be responsible for establishing the regulatory approach for the whole product lifecycle and leave your regulatory legacy in the department that you can build underneath you.

As Regulatory Affairs Manager, you will be responsible for setting up regulatory plans aligned with the business strategy and be the “go-to” person for regulatory affairs activities internally and externally. As well as defining and implementing the European and US regulatory strategy, you will also be responsible for leading the current team and make the RA department more robust by developing processes and people.

# The responsibilities

- Lead agile project management and regulatory activities i.e. architectural design, re-using components, differences between medical software device in EU and in US
- Establish the regulatory approach and manage the full product lifecycle
- Set up, initiate and implement Regulatory Plans aligned with business strategies in collaboration with the Chief Clinical and Regulatory Officer
- Work in collaboration with the product development team on product claims, intended use and product safety

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# The responsibilities

- Coach, manage and provide guidance to the existing regulatory team
- Build and review documents/registration dossiers according to applicable regulations, requirements, and standards
- Support the R&D team to understand the difference on the level of rigor needed for IVDR submissions, US submissions and Design History Files
- Lead on region-specific needs e.g. Japan, China, LATAM
- Liaise with notified bodies, FDA and other regulatory agencies on submissions and questions raised
- And more...

As Regulatory 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.

# 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 4 years of experience in regulatory affairs working with medical devices or IVD devices
- Experience with software, software as a medical device OR embedded software
- Fluent written and spoken English
- Flexible, problem-solving and pragmatic mindset

# Get in touch

If you are interested in this exciting role, please send your application directly to **kristina@elemed.eu**

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