



eMed

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

Regulatory Affairs Specialist

KRISTINA@ELEMED.EU



The company

This well-established Danish company is a global leader in AI-driven technology and is paving the way in precision pathology software. This company has both products existing already on the market and products used for research purposes. 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, whilst staying in touch with your IVD device experience this could be just the opportunity for you!

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! If you raise your voice, you can be sure that you will be heard here and even have your ideas actioned dynamically and quickly.

A woman with curly hair is sitting at a desk, working on a laptop. She is wearing a blue zip-up top. The desk has papers, a coffee cup, and a small plant. The background is a warm, indoor setting with a window and some shelves.

The role

Based in their headquarters just outside of Copenhagen, 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.

As Regulatory Affairs Specialist, 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 have the autonomy over your work to make the RA department more robust by developing processes with the support of the Quality Manager.

In this position, you will also have the opportunity to touch upon other activities within Quality and work cross-functionally to support R&D.



A scenic view of a harbor with colorful buildings and boats. The image is split into two horizontal sections. The top section shows a red building with white windows and a dark roof against a sunset sky. The bottom section shows a harbor with several boats, including a red and white boat in the foreground, and colorful buildings along the waterfront.

The responsibilities

As Regulatory Affairs Specialist you will:

- Lead agile project management and regulatory activities i.e. architectural design, re-using components, differences between medical software devices in the EU and US
- Establish the regulatory approach and manage the full product lifecycle
- Set up, initiate, and implement Regulatory plans aligned with business strategies
- Continuously monitor and assess product features to maintain a high quality of products/services
- Work in collaboration with the product development team on product claims, intended use, and product safety
- Support the team with design control processes including Risk Management, Post Market Surveillance, and validation processes



The responsibilities

As Regulatory Affairs Specialist you will:

- Build and review documents/registration dossiers according to applicable regulations, requirements, and standards
- Support the R&D team to understand the difference in the level of rigour 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
- Plan and perform internal audits as well as supplier audits
- Support the optimisation of the Quality Management System
- And more...



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 of having a great work-life balance
- Multinational team spread across the world
- Opportunity to be part of the growth story and shape the organisation's quality culture



A photograph of two men in a professional setting. The man on the right, with a beard and long hair, is wearing a light blue button-down shirt and holding a tablet. The man on the left, with short dark hair, is wearing a brown sweater and looking at the tablet. They appear to be in a collaborative discussion.

Requirements

- Minimum 4 years of experience in regulatory affairs working with IVD devices
- European and/or US submission experience
- Fluent written and spoken English
- Flexible, problem-solving and pragmatic mindset

INTERESTED IN FURTHER CONVERSATION?

IF YOU ARE INTERESTED IN THIS
EXCITING ROLE, PLEASE SEND YOUR
APPLICATION DIRECTLY TO

KRISTINA@ELEMED.EU