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

Regulatory Affairs Lead

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The company

This well-established Danish company is a global leader paving the way in precision pathology software and IVDs. 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.

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 including NPD projects (design control coordination) and leave your regulatory legacy in the department.

As Regulatory Affairs Lead, 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 oversee activities within Quality such as coordinating design controls and work cross-functionally to support R&D.

The responsibilities

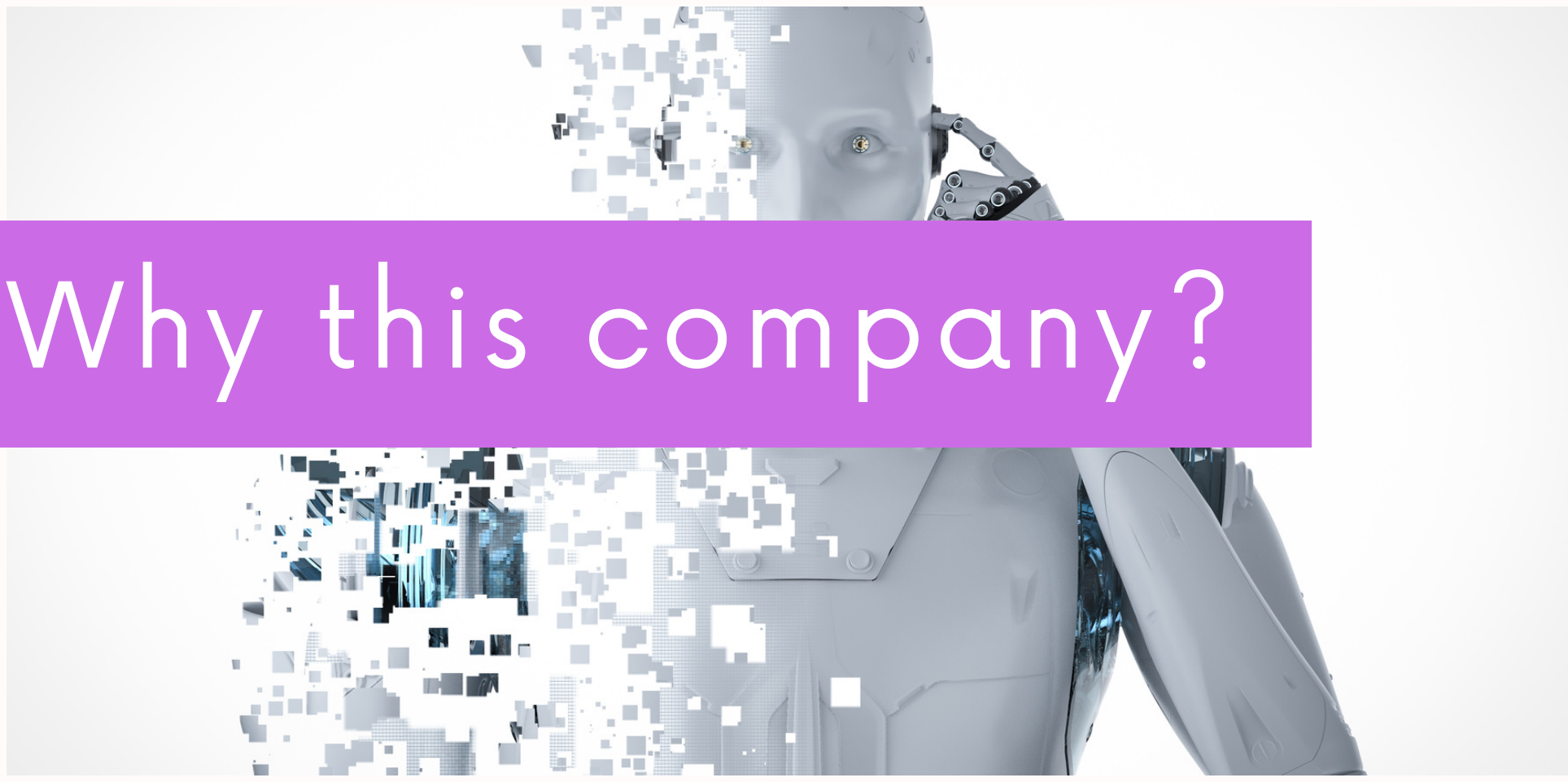
As Regulatory Affairs Specialist you will:

- Drive progress in NPD projects to ensure the meeting of deadlines and project transparency
- Establish the regulatory approach and manage the full product lifecycle
- Set up, initiate, and implement Regulatory Plans aligned with business strategies
- Lead agile project management and regulatory activities i.e. architectural design, re-using components, differences between medical software devices in the EU and in the US
- Build a Design and Development plan together with Product Management
- 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

The responsibilities

As Regulatory Affairs Specialist you will:

- Support the team with design control processes including Risk Management, Post Market Surveillance, and validation processes
- 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 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
- 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 strong work-life balance

- Multinational team spread across the world

- Opportunity to be part of the growth story and shape the organisation's quality culture

Requirements

- Minimum 4 years of experience in regulatory affairs working with IVD devices or medical devices

- Good knowledge of the full product lifecycle including contributing to NPD projects and CE marking/US submissions

- 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

VERONICA@ELEMED.EU

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