Head of Regulatory Affairs

Netherlands or Sweden or Denmark

The Company:

Have you ever been curious about working for a start-up?As Head of regulatory affairs, you will lead all regulatory affairs approval activities for a fast growing medical device startup, currently in stealth mode.

This start-up has recently been acquired by one of the world's leading medtech companies, so this role offers the best of both worlds; a hands on position with a lot of responsibility as the Head of RA AND the financial stability and job security associated with working for a corporate! This is a role that offers strong career development to build a team and the chance to be part of a growth journey; all with minimal risk.

If you've got an entrepreneurial spirit, and are motivated by the prospect of building something new, and getting highly innovative products to market, quickly, this is a great opportunity for you!

We are looking for a HEAD OF REGULATORY AFFAIRS, someone with a strong regulatory background, a strategic mindset and solid understanding of regulatory processes and go-to market strategy.

In this role, you'll be more than just another number, having the chance to really be responsible for bringing a new and disruptive product to the market. We are looking for self-starters who like the hands-on responsibility and independence this role would bring.

In this role as Head of regulatory affairs; your main goal would be to establish, develop and implement the regulatory strategy for the regulatory approval (CE marking) of this start-ups medical device, a highly innovative Active Implantable Medical Device (class III). You will also be the main liaison with regulators, and will need good communication skills to build a strong working relationship with these stakeholders. This is a highly independent role, with a lot of accountability.

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As Head of regulatory affairs you will:

- Lead regulatory affairs activities during the development of this highly innovative product (Class III Active Implantable Medical device)
- Develop the regulatory strategies for product approval in Europe according to MDR
- Represent the company towards external Regulators, Notified bodies and Competent Authorities
- Manage and build good relationships with Regulatory Authorities and corporate colleagues
- Act as regulatory expert for your product, providing guidance to regulatory colleagues and other internal partners worldwide
- Regulatory Intelligence - monitor the regulatory climate in Europe, keeping abreast of upcoming changes and address them where appropriate

Are you a regulatory professional, with a good understanding of taking a risk based approach, strong communication skills and the ability to navigate the grey?
If you're somebody who thinks in pragmatic solutions rather than restrictions, we want to hear from you!

Skills required for this role:

- 8+ years experience in regulatory affairs for medical devices (class IIb-III active or non active suitable)
- Engineering/Scientific/Technical university degree
- CE marking experience, having brought a new product to market
- Experienced having worked on MDR implementation and working knowledge of MDD or AIMDD
- English speaking skills PLUS (Dutch, OR Swedish OR Danish)

To be considered for this role, please send your CV to elena@elemed.eu