REGULATORY AFFAIRS SPECIALIST

Posted on 25 januari, 2023

Company Name Neoventa Medical

Location Gothenburg

Job Description

Reporting to the CTO, you will ensure the regulatory requirements, applicable for the company and its products, are continually updated.

You will be responsible for maintaining and assessing the international market's regulatory framework and the regulatory activity planning for any new or changed products according to local regulations. You will communicate with authorities regarding product changes and in case of product recalls and/or vigilance reporting.

In this role you will be part of a collaborative team in a global context and you will be working close to the QA team.

Responsibilities

- Plan and perform vigilance activities, e.g., authority contacts, recalls, advisory notices etc.
- Communicate with Notified Body and authorities regarding substantial system changes and new product designs
- Review design dossier/technical file and labelling for regulatory approval at new designs and change managements
- Keeping list of applicable laws and regulations updated
- Ensure that processes needed for regulatory compliance in the quality management system are documented
- Ensure the promotion of awareness of applicable regulatory requirements and quality management system requirements throughout the organization
- Participate in new development projects to perform review of device-specific and region-specific regulations applicable for the new device
- Participate in projects related to entering new markets to identify applicable and necessary region-specific regulations and approvals
- Responsible for the Annual PMA reporting

Experience

- Experience within regulatory area and/or technical documentation for medical devices.
- Familiar with applicable product standards
- Good knowledge of medical device registrations
- Fluency in the English language and is comfortable communicating in Swedish, in speech and in writing

Key Skills desired

- ISO 13485
- FDA regulations
- UK regulations
- EU regulations
- MDD/MDR
- Product standards

Why Neoventa

Neoventa is embarking on an exciting growth journey. As the company expands you will have a great opportunity to learn, develop and make a difference along the way. Your daily work is in the newly decorated HQ office in Mölndal, but you will also be able to work partially from home. Neoventa has a collective bargaining agreement, with additional benefits including individual pension advice and generous health benefits. A further satisfaction of working at Neoventa is the shared contribution to the joy of safe childbirth.

To apply

This recruitment is handled by our recruitment partner, Moveup Consulting AB. To apply, please send your CV and a cover letter to Tom Bergqvist at tom.bergqvist@moveup.se.

If you have questions regarding Neoventa Medical or this open position, please contact Tom at 0733-87 27 22. We are screening applications continuously. Please send your CV and cover letter no later than 19th February.

By submitting your application, you also consent to us storing your personal data, including CV & cover letter and that we have the right to share this information with third parties (our client). You can revoke the consent whenever you want.

Om företag

Neoventa Medical AB is a Swedish medical device company founded in 1997. Neoventa provides innovative fetal monitoring solutions and services that improve obstetric care. Our solutions are

designed to promote patient safety through enhanced decision support together with a structured workflow. Every day across the globe, health care professionals use our unique solutions to ensure a good start in life.

Our core competence lies in using the Stan fetal and maternal monitor to perform evidence-based ST analysis of the fetal ECG as an adjunct to CTG, “a second pair of eyes” during childbirth. We are also the provider of disposable fetal scalp electrodes for internal fetal monitoring under the brand Goldtrace. Another important area of business is a comprehensive education and training program, Neoventa Academy, which includes e-learning with certification.

Expanding our business, we’re recruiting a Regulatory Affairs Specialist, to be placed at Neoventa HQ in Mölndal.

www.neoventa.com

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