

QUALITY ENGINEER

Posted on 17 januari, 2023

Company Name Neoventa Medical

Location Gothenburg

Job Description

Reporting to the head of quality, you support in the development and the improvement of the company quality management system to achieve business improvements and to ensure regulatory compliance. You provide continuous support to the rest of the company with documentation to assure compliance with internal processes and policies, regulations, ISO 13485, and other applicable standards.

Expanding our business, we're recruiting a Quality Engineer, to be placed at Neoventa HQ in Mölndal.

Responsibilities

- Assist in implementation projects related to quality assurance and regulatory compliance
- Plan and perform vigilance activities, e.g., authority contacts, recalls, advisory notices etc.
- Contribute to communication with Notified Body and authorities regarding substantial system changes and new product designs
- Assist in the review design dossiers/technical files and labelling for regulatory approval at new designs and change managements
- Keeping list of applicable laws and regulations updated
- Support with Product Risk Management
- Participate in projects related to entering new markets to identify applicable and necessary region-specific regulations and approvals
- As part of the Quality and Regulatory team ensure the promotion of awareness of applicable regulatory requirements and quality management system requirements throughout the organization
- Contribute to the performance of internal and external audits

Experience

- At least 1-2 years of experience, or equivalent knowledge, within quality or regulatory area and technical documentation for medical devices
- Familiar with applicable product standards
- Some knowledge of medical device registrations and/or product risk management would be

an advantage

- Fluency in the English language and is comfortable communicating in Swedish, in speech and in writing

Key Skills desired

- Product standards
- ISO 13485
- ISO 14971
- FDA regulations
- UK regulations
- MDD/MDR
- Risk Management

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.

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. www.neoventa.com

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