

QUALITY ENGINEER - MEDICAL DEVICES

Posted on 22 april, 2020

Company Name Moveup Consulting AB

Location Göteborg

Job Description

We are now recruiting a Quality Engineer

If you want to make a difference in the quality of life of patients, you are welcome to join OneMed as a Quality Engineer reporting to the Quality & Regulatory Director. This position is based in Göteborg.

The purpose of this position is to support OneMed with knowledge of relevant product standards, clinical use of products, available raw materials as well as applicable packaging, production and sterilization processes. You participate in the maintenance and further development of ISO 13485 quality management system.

Key Responsibilities

- Assist in setting up technical documentation needed to CE mark own-branded medical devices and maintain regulatory compliance.
- Review and approval of Design Inputs, Labeling, Design Outputs, Validation reports.
- Risk analysis of medical devices.
- Monitor quality issues, collect post-market feedback as well as act as Product Area Complaint Handler for defined own-branded product groups.
- Strong support to interpret the content in MDR (Medical Device Regulation)
- Support in internal/external audits

Qualifications

- Master of Science (Civilingenjör) or Bachelor's degree. A major in chemistry or microbiology is a plus.
- Relevant work experience in related field of medical or technical devices. QA Engineer experience or a background as a Technical Product Manager is desirable.
- Experience of working with quality management and/or product development, being part of creating product specifications and evaluating product quality.

- Preferably knowledge of textile technology (e.g.: nonwovens, renewable materials) or polymer technology.
- Preferably knowledge of industrial sterilization methods, process validation and microbiology.
- Advanced computer skills using Microsoft Office applications.
- Strong problem solving and analytical skills.
- Excellent Team Player, working across various functions.

To be successful in OneMed you enjoy working in multicultural groups and you always involve in-country locals in dialogue about how to get things done. You are not afraid to challenge the way things are done and you always assign the highest priority to improving patient outcomes.

What can we offer you?

We offer you a chance to work in a creative and developing environment with a lot of freedom under responsibility. The role is important for the day-to-day operations of the business and there are many opportunities to develop in an international environment. Our employees are all valuable to us and we strive to have a good mix of people with different backgrounds and experiences, creating a versatile and dynamic workplace.

If you have questions regarding OneMed or this open position, please contact our recruitment partner at Moveup Consulting AB, Tom Bergqvist at tom.bergqvist@moveup.se or 0733 – 87 27 22.

We are looking forward to have your application, CV and Cover letter, sent to tom.bergqvist@moveup.se

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

Om företag

Welcome to Europe's leading healthcare partner. We provide consulting services to optimize processes, tools to support decision making and a comprehensive range of medical supplies. Healthcare providers across Europe turn to us to better meet their patients' needs. We help them improve patient outcomes, lower the total cost of care, and achieve superior environmental and CSR results. As a OneMed partner, you receive a comprehensive solution from a company that understands the unique demands of healthcare. Through care improvement initiatives, brand-neutral decision support, healthcare procedure training, product range optimization and streamlined ordering procedures — we help our customers

improve patient outcomes at a lower total cost and with greater resource efficiency. Our portfolio comprises more than 40,000 products from leading global suppliers. We also develop our own exclusive brands: evercare® and SELEFA®. OneMed is present in 8 countries and has a turnover of more than SEK 5 billion annually.

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