

# QA/RA DIRECTOR

*Posted on 7 mars, 2022*

**Company Name** OneMed AB

**Location** Gothenburg

## Job Description

*If you want to make a difference in the quality of life of patients, you are welcome to join OneMed as a QA/RA Director reporting to the Director of Private Label.*

In this position you will be a leader and support and motivate the members of the Quality and Regulatory Team. You will ensure that OneMed Products AB fulfill the Medical Device Regulation and you will have the technical responsibility for the brands Evercare, SELEFA and Embra. In this role you will establish technical documentation for all products in relation to ISO standards and the existing Medical Device Regulation. You will make sure that the quality system is fully utilized and contains all the valid documentation and you will represent top management in regulatory management review meetings. This position will be based in our office in Göteborg.

## Key Responsibilities

- Support OneMeds organization with deep product knowledge such as: relevant product standards, clinical use of products, available raw materials as well as applicable packaging, production and sterilization processes provide good basis for successful performance
- Own all external audits and the relationships with the Notified Body
- Act as Person Responsible for Regulatory Compliance, PRRC
- Ensure that OneMed establish technical documentation needed to CE mark their own-branded products
- Review and approval of Design Inputs, Labeling, Design Outputs and Validation reports
- Ensure stable quality of defined own-branded product groups according to the process and relevant stakeholders
- Ensure to monitor all quality issues and provide market feedback as well as handling of complaints related to defined product groups in the role of Product Area Complaint Handler

## Qualifications

- Master of Science or Bachelor's degree in related field of medical or technical products and relevant work experience in related field of medical or technical devices

- Experience as a manager leading teams of Quality Engineers
- Experience 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
- Fluent in Swedish and English, both verbally and in writing

To be successful in OneMed and this position as a QA/RA Director you have a high degree of cross-cultural sensitivity: understand and can empathize with differences in people and cultures. You are not afraid of starting something and make adjustments along the way; not fearful of acting with a minimum of planning. When facing new problems you learn quickly. Most certainly you are not afraid to challenge the way things are done. You have analytical skills. However, maybe the most important, you are an excellent team player and you are being inspired by working across various functions.

### **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, Ann Rütt at [ann.rutt@moveup.se](mailto:ann.rutt@moveup.se) or 0733 – 44 09 00.

We are looking forward to have your application, CV and Cover letter, sent to [ann.rutt@moveup.se](mailto:ann.rutt@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**

#### **About OneMed**

*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.*

[www.onemed.se](http://www.onemed.se)

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