RA/QA Manager
°MEQU

About °MEQU
°MEQU has developed °M Warmer, a portable fluid warmer capable of heating infusion fluids and blood. °MEQU obtained CE marking for °M Warmer in October 2018. In accidents, there is often a need to administer fluids or blood to seriously injured individuals to restore normal bodily functions. By using °M Warmer, the chance of survival is increased, as infusion fluids and blood are heated to body temperature within seconds. This is essential in military field operations, civilian rescue missions, and, of course, in hospitals, including trauma centers and during surgeries. Among the company's customers are the Norwegian air ambulance, the British military, and most recently, Region Hovedstaden.
°M Warmer stands out significantly from its competitors, being small, lightweight, portable, and a robust device that is easy to use. Its user-friendly design has won several awards. °MEQU currently employs 12 dedicated employees who, in addition to optimizing the existing product, are actively involved in developing new, exciting products.

About the position
As QA/RA Manager at °MEQU, you will serve as the Head of Regulatory Affairs & Quality Assurance. You will have direct management responsibility for 2 QA Specialists and will yourself function as the RA Manager/Expert.

In the near future, you will be expected to take responsibility, particularly for °MEQU's MDR and FDA 510(k) processes. Going forward, you will work on a broader palette of regulatory tasks.

Thus, you will, among other things, act as the overall responsible party for:

- Compliance with applicable regulations (ISO 13485:2016, MDD, MDR, FDA, and UKCA, etc.)
- Liaison and ongoing dialogue with Notified Bodies and National Competent Authorities
- Ongoing regulatory monitoring
- Preparation and maintenance of product registrations in collaboration with pre-sales
- Ensuring that relevant legislation is addressed and implemented in the Technical Documentation
- Post-Market Surveillance activities, PMCF plan, PMS plan, PMS report, PSUR, CER
- Product registrations and renewal of existing ones as needed
- Supplier audits and participation in external and internal audits
- Optimization and maintenance of QMS
- RA/QA support for NCRs, CAPAs, and ECOs
- RA/QA guidance for the development process of new products
- Quality control of manufacturing processes and suppliers
- Providing RA/QA support for risk management
- Quality Management System reviews

Many of these tasks will naturally be performed by/in collaboration with the QA Specialists, for whom you are expected to be a good and present leader.

You will report to MEQU's CEO and also work closely with your colleagues in both R&D and Operations.

The position is an absolutely key role for °MEQU and it will certainly evolve along with the growth of the company.

Your qualifications
You likely have a higher technical, scientific, pharmaceutical, or healthcare-related education. However, what's most important is that you have extensive experience, especially in RA but also familiarity with QA within medical devices. It's crucial that you find it exciting to be involved in tasks covering both areas. It's a significant advantage if you have experience with MDR. Naturally, you have experience working under ISO 13485, MDR, QSR, and 510(k) compliance. Additionally, it's advantageous if you have experience leading specialists.

As a person, you are dedicated, and you thrive in a dynamic organization where everyone works together and helps each other across functions and responsibilities. Moreover, you find it appealing to be part of a startup company with the broad responsibility it entails. It's also important that you take responsibility, communicate effectively, and are proactive, while also working in a structured and systematic manner.

How to apply
°MEQU is collaborating with DEDENROTH on this recruitment, and Mia Danielsen is responsible for the recruitment process. To apply for the position, please send your CV to md@dedenroth-consulting.com.
You are also welcome to contact Mia at the above email address or phone +45 26178142.