QUALITY ASSURANCE & REGULATORY AFFAIRS DIRECTOR

Posted on 25 maj, 2021

Company Name Observe Medical

Location Göteborg

Job Description

We are now expanding the team with a Quality Assurance & Regulatory Affairs (QA/RA) Director. As our QA/RA Director you will own both the QA- and the RA-strategy and you will be a member of the Executive Management team, reporting to the CEO. You will be joining Observe Medical in an exciting phase where a lot of resources are being invested in developing both our product offering as well as our organization.

About the role

As QA/RA Director at Observe Medical you will be responsible to develop, drive and execute the QA & RA function. You will also support and enable the development of our commercial operations. We are looking for a senior colleague with extensive QA and RA experience, playing an important role supporting the local distribution and global commercialization of our product portfolio. You will furthermore support future launches of new medtech products to the market.

You will be responsible for ensuring product compliance and maintaining and improving the existing Quality Management System. You support the organization to meet all necessary requirements and regulations and you lead and participate in internal and external audits.

The position is placed at our office in Göteborg and will include both domestic and international travelling.

Qualifications

Your experience and demonstrated competencies:

- Relevant University degree
- Comprehensive experience (+5 years) of both operational and strategic QA- and RA-

responsibility in the medical device industry
- Experience in people management and developing of employees
- Demonstrated in-depth knowledge of relevant regulations, international standards and guidelines, such as ISO 13485, ISO 14971, MDD/MDR
- Preferably experience from taking new medtech products into the US and Asia
- Excellent communication skills in English (both written and spoken)
- Experience of working with medical device software would be an advantage
- Comprehensive experience from developing and delivering efficient quality management procedures processes is preferred
- Good working experience from risk management is meriting

Your personality:

- You are efficient, well organized, with a structured way of working
- You are a team player with the ability and willingness to handle multiple tasks and changes of priorities
- You are decisive and manage situations also with limited or conflicting information available
- You feel comfortable to align with colleagues to create practical and efficient processes
- You appreciate the high pace in an entrepreneurial and dynamic company

Apply today!

This recruitment is handled by our recruitment partner, Moveup Consulting AB.

We are looking forward to receiving your application (in English) as soon as possible. Selection and interviews are ongoing, and the position may be assigned quickly.

Please send your application (CV and Cover letter) to Tom Bergqvist at; tom.bergqvist@moveup.se

If you have any questions regarding Observe Medical or this open position, feel free to contact Tom Bergqvist at +46 733 87 27 22

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

Observe Medical is a fast-growing medtech company with global reach. The Company develops,

markets and sells innovative hospital products that contribute to improved patient outcome and a more efficient care system. Observe Medical is listed on Euronext Expand Oslo, Norway with headquarters in Oslo, and its operations is based out of Gothenburg, Sweden. Observe Medical has a direct sales organization in the Nordics for a broad product portfolio of hospital products within urine measurement, anesthesiology/ICUs and wound care, and a distributor network in Europe for Sippi® the Company's key product. Sippi® is the only automated digital urine meter with possibility for wireless data transfer to the hospital patient data management systems and hinders biofilm formation that can lead to urinary infections. Sippi® is CE marked and is currently being launched with focus on selected markets and hospitals in Nordics and in Europe.

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