QUALITY & REGULATORY AFFAIRS MANAGER

Posted on 13 augusti, 2024

Company Name Osstell

Location Göteborg

Job Description

Do you feel passionate about improving patient safety? Are you prepared to make a meaningful contribution to help dental clinics perform implant treatments with increased reliability? If so, we invite you to an exciting opportunity at Osstell, a global leader in implant stability measurement and osseointegration progress monitoring. We are currently looking for a highly motivated and talented individual to join us as ***Quality & Regulatory Affairs Manager****.*

In this role you will be part of a challenging and exciting journey shaping the company's future and taking the business to new heights. You will have a great opportunity to influence and improve the products we supply to the market whilst working in a dynamic and varied setting.

Responsibilities

- Maintain Osstells' quality management system and ensure compliance with applicable laws and regulations
- Responsible for monitoring market trends, industry, regulatory changes, best-practices, and requirements within QA and initiate, inform and suggest activities to the Management Team
- Ensure that processes needed for the Quality Management System are documented
- Find, analyze, initiate, and coordinate improvements together with relevant stakeholders. Responsible and lead for QA improvements and set a yearly plan. Fostering a culture of continuous improvements and excellence
- Support the organization in all matters regarding quality assurance processes, and thereby provide guiding support. Provide coaching and education to colleagues regarding QMS.
- Manage product complaints and nonconformance procedures. Regularly monitor issue trends, inform relevant stakeholders and prepare NC reports monthly.
- Organize and lead the CAPA handling processes.
- Participate in the Group's QA/RA regular meetings and other initiatives upon demand.
- Ensure products are registered in relevant country in EU.
- Coordinate IFU translations and reviews.

Requirements

- Experience from medical devices Quality Assurance, and Regulatory Affairs (EU)
- Excellent documentation and communication skills, in English as well as in Swedish

Additionally, we are looking for someone who has:

- A strong sense of ownership and accountability
- Ability to plan and prioritize multiple work activities
- A collaborative and flexible attitude
- A passion for continuous improvement and innovation

It is an advantage if you have:

- Audit experience
- QA Product Development experience
- Experience from Medical Devices Software/Electronics and Cybersecurity

Why Osstell?

Join our mission to **help clinicians provide each patient with optimal time to teeth**

Osstell has a long-term commitment to our customers, employees, and partners. We are in it for the long run. Our core values states what we always should focus on, Customer value, Entrepreneurship, Competence & cooperation, Innovation and Sustainability. The motto is People have priority.

Joining Osstell you will be part of a company that has a clear strategy for growth on a global market. You will be working in an international environment in a professional and highly competent team, supported by world leading partners. Osstell is headquartered in Gothenburg, with a centrally located office. We can offer the advantages of being a smaller company with high individual impact, combined with the stability of being supported and owned by the W&H Group.

This role will give you the opportunity to truly develop, grow and broaden your skills.

Application

This recruitment is managed by our recruitment partner, Moveup Consulting AB. To apply, please

send your CV to Tom Bergqvist at tom.bergqvist@moveup.se

If you have questions regarding Osstell or this open position, please contact Tom at +46 733 440 900 or tom.bergqvist@moveup.se

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

Osstell is the global leader in implant stability measurement and osseointegration progress monitoring. Since the company was founded in 1999, over thousands of scientific studies have been published confirming the clinical value of Osstell's proprietary Resonance Frequency Analysis (RFA) technology and the Osstell ISQ scale (Implant Stability Quotient).

In 2018 Osstell became a part of the W&H Group, a global leader in the development and manufacture of medical technology products with over 1300 employees. Osstell is headquartered in Gothenburg, Sweden, the birthplace of dental implants. Our product solution is available in more than 70 countries, through our own presence and a vast network of distributors for the rest of the world. We empower dental professionals by providing objective implant stability measurements to provide each patient with optimal time to teeth, and improve patient confidence.

W&H Group

Headquartered in Bürmoos, Austria, the international W&H Group is a world leader within dental industry. Passion and innovation are motor of the medical device manufacturer. Innovative product and service solutions, a modern corporate structure, a strong focus on research and development as well as social responsibility make W&H a locally and globally successful family business.

More than 1,300 employees worldwide contribute to the production of hardware and software products for use in dental practices, clinics and laboratories and in oral and maxillofacial surgery, helping to ensure the safe and gentle patient care.

The dental precision instruments and high-end solutions are developed and produced at production sites in Austria, Italy and Sweden. With worldwide subsidiaries and a comprehensive network of distribution partners, W&H is represented in 130 countries. The company's focus is on export. Key sales markets include the USA, Europe and Asia.

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