

QA/RA MANAGER

Posted on 8 september, 2021

Company Name Integration Diagnostics

Location Göteborg

Job Description

In this position you will be responsible for our Quality Assurance and Regulatory Affairs. You work in close cooperation with all functions within the company.

You will have a great impact on how the work is set up. Your daily work is conducted in a dynamic international working environment.

Your role

- Responsible for the company's QMS and ensure that quality requirements from the ISO 13485 and QSR are met providing a basis for regulatory compliance with MDD, MDR and FDA standards
- Plan, improve and implement changes to the company's QMS
- Implement MDR
- Be the driver of regulatory approvals for existing and new markets
- Supporting sales, operations and R&D with quality and regulatory input
- Lead and/or participate in external audits
- Perform internal QA trainings and audit preparations
- Future member of IDSAB's management team

Qualifications

- MSc in Engineering or similar
- Fluent in English
- Experience of working with ISO 13485 and Medical Devices
- Experience from medical device product development and management systems
- Regulatory experience from medical device registrations world-wide is considered an advantage but is not mandatory

We can offer you an exciting and challenging job and to succeed in this role, you need to have a sense for the right level of Quality Assurance and a strong drive to improve the company's work-flows in order to enhance the business. You are action oriented with great planning skills and are interested to interpret and understand relevant standards for the medical device market. Since we are a small company, you will be a natural part of the company's decision making. We can offer you both internal and external education within the QA/RA area.

To apply

This recruitment is handled by our recruitment partner, Moveup Consulting AB. To apply, please send your CV and a cover letter to tom.bergqvist@moveup.se

If you have questions regarding Integration Diagnostics or this open position, please contact Tom at +46 (0)733 87 27 22.

We are screening applications continuously. Please send your CV and Cover letter no later than 30 September.

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

Integration Diagnostics and its core products, Penguin RFA and Osseo 100 measures dental implant stability to enable clinicians to decide when to load an implant. The technique has been developed in close cooperation with clinicians and experts in the field of dental implantology.

The products have been received extremely well by the market. Continued rapid growth is expected in the future. Resonance Frequency Analysis (RFA) and the measurement unit Implant Stability Quotient (ISQ) were introduced into the dental implant industry in 2001 and are now established methods of measuring implant stability and osseointegration.

In 2015, in response to the dental community's need for an accessible ISQ measuring system, Integration Diagnostics Sweden AB (IDSAB) was founded. Sales have developed rapidly with clients today in + 70 countries globally.

*On November 30, 2018, Integration Diagnostics Sweden AB (IDSAB) became part of the Japanese company Nakanishi Inc., a leading company of professional dental instruments with the world's top-share brand "**NSK**". All its products are developed and manufactured in Japan and distributed to 135 countries around the globe. The NSK Group has 14 subsidiaries worldwide and has established a strong global sales network.*

Consultant Name Tom Bergqvist

Consultant Number 0733 - 87 27 22

Consultant Email tom.bergqvist@moveup.se

Cosultant Linkdin <https://www.linkedin.com/in/tombergqvist/>