

VP QUALITY ASSURANCE & REGULATORY AFFAIRS

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Company Name Coala Life AB

Location Sverige

Job Description

Do you want to be part of a small, global and fast growing medtech-company in Uppsala with the vision to win the fight against the world's leading cause of death? Are you a curious and committed person who is driven by the opportunity to work with the best in the industry and to take great responsibility?

Then the job as our new VP Quality Assurance and Regulatory Affairs at Coala Life is for you.

About the job

As our VP Quality Assurance & Regulatory Affairs you set the overall strategic direction for Quality Assurance and Regulatory Affairs. You work collaboratively across multiple functions and external governing bodies to ensure COALA products and services meet the needs of our patients, customers, and remain compliant to global regulations.

As a member of the Executive Leadership Team you maintain our Company Quality Management System (QMS) according to legal requirements and EN ISO 13485, US 21 CFR 820 (QSR), EU MDD/MDR and other applicable global regulations.

Your accountabilities

- Lead all Global Regulatory Affairs and Quality functions at COALA while serving as a member of the Executive leadership team; ensures corporate goals of introducing new products and supporting existing products in the marketplace are met
- Establish regulatory and quality strategy, including long term Company vision and ensure alignments with all functions in the organization. Ensure the development and execution of regulatory and quality strategies and plans to enable efficient global development of products in the portfolio
- Represent the Company as Management Representative and Official Correspondent to FDA and other global certifying bodies

- Establish relationships with governing bodies and develop internal/external networks to facilitate collaboration and successful execution
- Design and implement regulatory strategies and oversight in support of submissions, device labeling and promotional materials
- Maintain external visibility to new and changing regulatory trends and guidance as input to the overall COALA strategies
- Perform due diligence activities for acquisitions, OEM and co-marketed products
- Work collaboratively with key internal stakeholders such as Research & Development, Clinical, Operations and Marketing globally
- Participate actively as a member of the COALA executive management team and embraces the COALA culture
- Attract, develop, engage and retain a high performing team

You need to have

- Leadership experience within medical device industry
- Experience from a global environment in particular United States and Europe
- Proven track record of establishing effective relationships with regulatory agencies, including the FDA
- Experience securing approvals for complex medical devices and novel technologies
- Excellent communications skills across all levels of the organization with the ability to influence through constructive and collaborative means
- University degree required

Are you the one we are looking for?

We are always looking for rare talents. You have a sixth sense to make things happen, fast, and you love technology. You appreciate the high pace in a small and dynamic company and you have a really good knowledge of both quality and regulatory requirements. Being our regulatory expert, you are well organized and you have a structured way of working. However, maybe the most important, you must have an ability and willingness to handle many different tasks and changes of priorities.

What can Coala offer you?

At Coala, you will have a great opportunity to develop in a global company with really high ambitions. Coala has received many awards and is ranked as one of the most exciting and promising

health care growth companies in Sweden. Our new office in Uppsala, in walking distance from the train-station, will be your base but you can also work partially from home. This is a great opportunity to use and to strengthen your global experience both in quality and regulatory.

Apply today!

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 Coala Life or this open position, please contact Tom Bergqvist at +46 (0)733 87 2722

By submitting your application, you also give your consent to storing your personal information, including CV & Cover letter, and that we own the right to share this information with third parties (our client). You can withdraw the consent at any time.

Om företag

Coala Life was founded in Sweden with a mission to develop patient-centric solutions powered by smart algorithms. The solutions aim to digitally transform the field of cardiac diagnostics, to help win the battle against the world's leading cause of death – heart disease.

The COALA Heart Monitor is used by thousands of patients and more than 350 connected healthcare providers to help remotely detect and diagnose heart disease, as well as alleviate worries. Our unique innovations have received multiple prestigious awards and supported by over USD 30 million in funding.

We make it possible for everyone to monitor and analyze their heart. Anytime, anywhere.

www.coalalife.com

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