

QUALITY ASSURANCE AND REGULATORY AFFAIRS ASSOCIATE

Posted on 21 december, 2022

Company Name Coala Life

Location Uppsala/Stockholm

Job Description

Do you want to be part of a small, global, and expansive MedTech-company in Uppsala with the vision to win the fight against the world's most common causes 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? QA/RA Associate at Coala Life can be you.

We're expanding our quality department with a Quality Assurance and Regulatory Affairs Associate (QA/RA Associate) who will work as an integral part of the quality and regulatory team to maintain and improve our internal systems in an efficient way with the highest quality in the management of our products. The QA/RA Associate will work in all aspects of quality systems for the product.

About Coala

[Coala Life](#) is a flexible and agile company in an expansion phase, where the initiation and implementation of changes to our processes are considered a natural part of the work. We believe that you are a curious, hands on, and organized problem solver with a passion for efficiency, process, and improvements.

In the role of QA/RA Associate, you will:

- Provide continuous support to rest of the company with documentation to assure Coala Life's compliance with internal policies, FDA regulations, ISO 13485, standards, and other governmental regulations
- Participate in and lead Quality and Regulatory activities
- Assist in maintaining QMS and ability to provide training with regulatory and quality requirements
- Support management activities in partnership with cross-functional departments to ensure timely implementation of document change requests
- Receive, categorize, and process PMS data related to Coala products
- Communicate well informed answers to different parts of the company and third parties
- Maintain accurate and timely correspondence and data

- Assist in the authoring and review of SOPs and applicable policies
- Be able to take on and handle different Quality and Regulatory tasks when needed

Qualifications

- 3-4 years' work experience in Quality and/or Regulatory or other position in a regulated industry
- Focused individual with a keen attention to detail and with a high level of accuracy in your work
- Proactive, service-oriented, and self-driven
- Team player with good communication skills
- Proficient in written and spoken English and preferably Swedish
- Competent user of MSOffice
- Flexible and adaptable to a fast-paced work environment
- Reliable, organized, and able to focus on effective time management

Are you the one we are looking for?

We are always looking for rare talents. You have ability to make things happen, fast, and you love technology and design and of course you have a passion for doing good. You appreciate the high pace in a small and dynamic company, and you have experience of both quality and, preferably, regulatory requirements. Most certainly you are well organized, and you have a structured way of working. However, maybe the most important, you are a team player and you must have an ability and willingness to handle many different tasks and changes of priorities. You feel comfortable to align with colleagues to create practical and effective processes.

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 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 experience 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 daniel.kremer@moveup.se

If you have questions regarding Coala Life or this open position up until January 3rd, please contact Tom Bergqvist at Moveup on +46 (0)733 87 2722

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

Coala Life AB is a fast-growing Swedish medical technology company focused on cardiac diagnostics and mobile health. We develop and market patented products. The head office is located in Uppsala, Sweden. Our Coala Heart Monitor is a medical device launched in early 2017.

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