

QUALITY ASSURANCE AND REGULATORY AFFAIRS MANAGER

Posted on 12 mars, 2020

Company Name Moveup Consulting AB

Location Uppsala

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 a Quality Assurance and Regulatory Affairs Manager (QA/RA Manager) at Coala Life is for you.

About the job

As our QA/RA Manager you will have a really broad scoop of responsibilities, all of them related to the regulatory compliance. You establish and implement product registration strategies and plans for new markets and you lead the work of getting product documentation in compliance with MDR. Being part of a small company also calls for an operational (and truly flexible) mindset. Deviation management, complaints, CAPA, internal/external audits and risk management are parts of your daily work. You also handle registration, updates and re-registration of our products.

In this position you also keep contact with relevant competent authorities and Notified body, you contribute in the post market surveillance and of course you support colleagues with quality and regulatory questions as kind of the go-to-person or subject matter expert.

You need to have

- University degree
- Experience in quality assurance and regulatory affairs working with medical devices controlled by MDD/MDR and FDA.
- Good understanding of applicable medical device regulations and standards.
- Some knowledge of labelling requirement within the medical device industry.
- Experience of working with medical device software would be an advantage.

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 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 a really good knowledge of both quality and regulatory requirements. Being our regulatory expert you are most certainly 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. You feel comfortable although you cannot always do much better than "good-enough".

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 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

Om företag

Coala Life was founded in Sweden with a mission to develop patient-centric solutions powered by smart algorithms. The company is on a mission 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 over 200 connected providers to help detect early signs of heart disease and alleviate worries. Our unique innovations have received multiple prestigious awards and supported by over USD 20 million in funding.

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

Consultant Name Tom Bergqvist

Consultant Number 0733 - 87 27 22

Consultant Email tom.bergqvist@moveup.se

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