Senior Regulatory Affairs Specialist

Lausanne or remote anywhere in Switzerland

Looking for a bit more flexibility after the pandemic? We are recruiting a senior regulatory affairs specialist to join a boutique medtech company in highly innovative class III devices.

This is a growing company with flexible work from home policies and a forward thinking approach.

The company

Located in Lausanne, a beautiful historical city overlooking the lake Geneva, is our client, a small but mighty company leading innovation in the Active Implantable Medical Device field. Owing to a growing pipeline of regulatory activities: regulatory Reporting under MDR, PMCF study monitoring, supporting CE marking and a new FDA submission; this company is at a highly dynamic and exciting stage of it's growth!

The opportunity

This is a brand new role, that has been created to support with a growing number of pre and post market regulatory activities! Are you a QA/RA professional looking for variety and the desire to bring something new and groundbreaking to the market for the first time? Everyone in this company is hands on, passionate about the product and changing lives.

This role will give you the chance to work with high risk class III devices, clinical trials, design, lifecycle management, and lots more. Working in a close knit environment, you have the opportunity to collaborate, learn a huge amount and be more than just a "number" in this company's story.

The responsibilities

As Senior Regulatory Affairs Specialist, your responsibilities will cover the A-Z of regulatory activities: classic country specific Regulatory affairs like CE marking/ working with FDA, Regulatory support to R&D during the new product development process, and Post Market Surveillance reporting.

Further details regarding your Responsibilities as senior Regulatory Affairs Specialist:

- Work on the preparation of the technical file to transition to the new Medical Device Regulation (the product was recently CE marked under MDD) and support its submission and follow up with Notified Bodies
- Collaboratively work on the next big project: an IDE and a PMA (no previous experience required)
- Complaint management and regulatory reporting to EC and NCAs
- Represent regulatory affairs on New product development projects, working in close cooperation with R&D
- Regulatory reporting for PMCF studies
- Manage translations of labels and manuals

(not exhaustive)

Are you passionate about a smaller environment with a community spirit? We want to hear from you!

The requirements

- 4+ years of experience in pre/post market regulatory affairs, medical devices
- Technical background
- Fluent English (German is a plus but not mandatory)
- Enthusiasm, desire to improve lives, creative thinker, flexibility

Are you interested in this exciting role?

Please send your application directly to elena@elemed.eu.