elemed

WORK FROM HOME, USA OR CANADA

DIRECTOR

REGULATORY AFFAIRS

GET IN TOUCH AT ELENA@ELEMED.EU

THE COMPANY

Join a well established, commercial stage company designing, developing and producing an innovative Class III active implantable medical device that changes the lives of patients. The device is CE marked, and preparing to submit for US approval.

With a strong KOL network in Europe and North America the company is looking for a hands-on Senior Regulatory Affairs professional to represent and support the company with the execution of its US regulatory strategy and be the operational main point of contact with the US FDA.

This is a great opportunity to work on an AIMD that has no predicate (making it unique and challenging!), have great exposure to the senior leadership team (you will report to the Global VP of QA/RA, and to be part of a company's growth story.

If you are looking for a big corporate role with a large team to manage, this position is not for you. This role is all about being hands on with the product and working closely with your global counterparts in Europe (Switzerland), where everyone is working towards the same goal.

In this role you'll be a trusted advisor to the Global VP of QA/RA and leadership team and the operational POC with the US FDA. If you're looking for a role that gives you flexibility and autonomy to use your US FDA experience in a new context, this is one for you! You'll enjoy a wide variety of responsibilities covering both pre- and post-market activities for the USA, for the company's existing portfolio, changes and supplements.

THE RESPONSIBILITIES

As Director Regulatory Affairs USA you'll report to the Global VP of QA/RA. Your responsibilities will cover:

- One region (the USA) - all products, systems and regulatory activities. You'll be interfacing heavily with the Global Director of Regulatory and Compliance and working in partnership with the global QA/RA team in Europe (Switzerland)
- You'll operationally represent the company as the operational lead for all pre- and post market activities specifically for the United States
- Your goal: to get product approvals. You'll be supporting pre-market submissions (PMA's) and be responsible for post-market supplements to the FDA, ensuring timely renewals and registrations for the US in accordance with FDA timelines.
- You'll evaluate the impact and implication of process and design changes on US regulatory compliance and whether there is need for submission
- You'll support the communication with the FDA through activities such as; regulatory correspondence, supporting the formulation of responses to deficiency letters, supporting 3rd party external audits/ FDA inspections, etc.
- As the company's expert for the US, you'll provide US input and perspective on the strategies that are developed for US regulatory approvals
- Support the review of promotional materials intended for the US and and formulate product labeling for new products
- Ensure that the DHF/DMR for the US is kept up to date

(not an exhaustive list)

THE REQUIREMENTS

- 6+ years experience with new product introductions/ supplements in the US market for medical devices
- 510(k), De novo or PMA experience
- Experience with active medical devices
- Hands on and strategic thinker.

INTERESTED IN FURTHER CONVERSATION?

PLEASE SEND YOUR CV TO ELENA@ELEMED.EU TO ARRANGE A CONFIDENTIAL CAREER DISCUSSION.