elemed

Zug, Switzerland

SENIOR REGULATORY AFFAIRS SPECIALIST

Get in touch with kristina@elemed.eu

Do you have experience in pre OR post-market regulatory affairs? Are you looking for an opportunity to take your responsibilities to the next level? Do you enjoy working with complex medical devices? If you answered yes to even just one of these questions, take a look at this fantastic opportunity!

THE COMPANY

Present in over 90 countries globally, this company has a brand that precedes them and the largest portfolio of innovative products in their field. From Class I to Class III, non-active to active, implantable to non-implantable, you can be certain you will learn something new every day! Despite being a large global player with over 10,000 employees around the world, you can still see the big picture of the business and make a real impact.

This company is dedicated to improving the health and well-being of their patients across the globe with high ethical standards. But it doesn't end there. They understand the importance of acknowledging and rewarding the achievements of their employees as well as investing in their development with various internal progression programs.

THE OPPORTUNITY

Due to a growth spurt within the company, a new role has been created for a strong regulatory affairs professional to be responsible for the DACH & Liechtenstein region and uphold AR responsibility in Switzerland. This is an opportunity to own your own processes within a large organisation and more importantly, make key decisions for your region. You will have a broad range of responsibilities including navigating new challenges and requirements within RA for the region.

THE QUALIFICATIONS

As Senior Regulatory Affairs Specialist you should have:

- 5+ years experience in pre or post-market Regulatory Affairs for the medical device industry
- Experience with CE marking AND/OR 510(k) submissions is a bonus
- Fluent speaking, reading and writing in English AND German

THE RESPONSIBILITIES

As Senior Regulatory Affairs Specialist you'll have the following responsibilities

- Manage the lifecycle for the portfolio of products within the DACH and Liechtenstein region
- Establish, manage and develop the Swiss Authorised Representative office on behalf of the company
- Develop processes to ensure the compliance of all devices throughout the lifecycle for the DACH region
- Support key relationships with European Authorities, notified bodies and International competent authorities
- Manage notifications of medical devices to the relevant local authorities such as Swissmedic in compliance with the national legislation
- Contribute to the regulatory intelligence and regulatory policy activities within the company
- Be the "go-to" person/subject matter expert for the DACH region and act as the primary point of contact for the commercial teams in the region
- Perform various activities such as Field Safety Corrective Actions, reviewing and approving promotional materials, verification of labelling and packaging, conduct change evaluations





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ARE YOU INTERESTED IN THIS POSITION?

Please send your application directly to kristina@elemed.eu