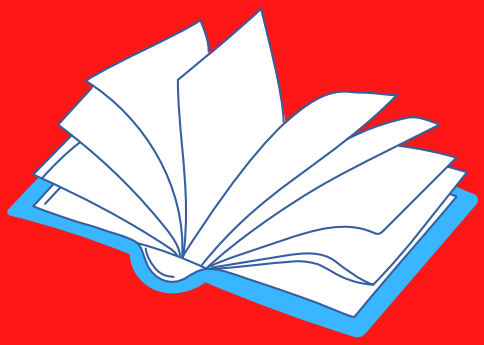
ZUG, SWITZERLAND

SENIOR REGULATORY AFFAIRS MANAGER

THE COMPANY



Are you experienced with EU and/or US submissions for medical devices and want to develop your career? Come and join a growing company located in Zug! Located in the classic natural beauty of Switzerland, the town has great links to the buzzing city of Zurich with the train station just 200m and motorway nearby.

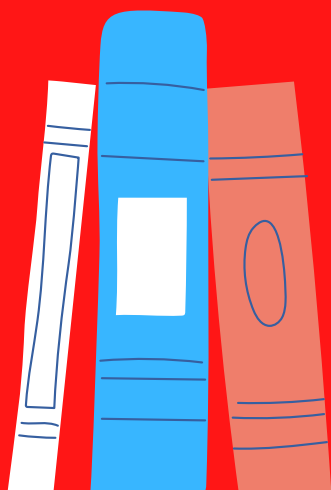
This company is developing and manufacturing Swiss-made products that are being delivered directly to intensive care units in hospitals and have supported the treatment of COVID-19 patients. This company has a broad portfolio of devices and accessories but they continue to innovate and look to the future with a commitment to become a global-leader in their field.

THE OPPORTUNITY

As regulatory affairs manager, you will be right at the centre of where all the key decisions are made, and where the development teams sit. You will be joining an expanding regulatory team and, with this company's flat hierarchy, you will report directly to the VP QARA.

In this position, you will oversee the entire lifecycle from start to finish as well as develop your skills in EU and US submission. The broad portfolio gives you the opportunity to work with active & non-active medical devices, giving you the chance to learn a lot!

Do you love collaborative work environments? You'll have the chance to join a multicultural company, where learning from each other, teamwork and "having fun" is at the heart of their culture. The company has regular team "coffee and learn" meetings where you can take charge of your professional development and improve in other areas of interest led by your fellow colleagues.



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YOUR QUALIFICATIONS:

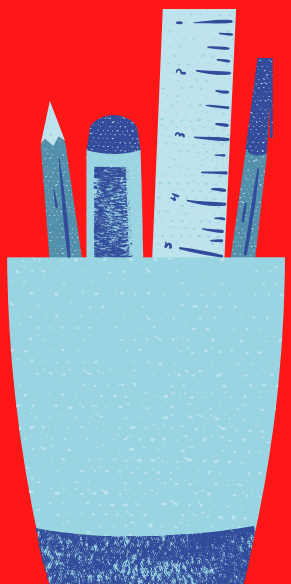
As Regulatory affairs manager you should have

- 4+ years experience Regulatory Affairs in the medical device industry
- Experience with CE marking AND/OR 510(k) submissions
- Fluent speaking, reading and writing in English and German

YOUR RESPONSIBILITIES:

As Regulatory Affairs Manager you'll have the following responsibilities

- Manage your own portfolio of products through development and lifecycle management processes globally
- Work on Innovation projects as the regulatory representative, providing input regarding risk management, standards and guidance documents
- Support key activities such as vigilance
- Closely collaborate in multi-disciplinary teams from Regulatory, Quality, Technical, Marketing & R&D on new product development projects and international product launches
- Support key relationships with European Authorities, notified bodies and International competent authorities
- Be responsible for technical documentation review, and support the creation and continuous improvement of regulatory related processes
- Create new and maintain existing registrations in EU and US, follow the changes to the MDR and support with testing activities related to the standards relevant for your product.
- Act as PRRC for the company



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INTERESTED TO EXPLORE THIS FURTHER?

Please send your CV to Kristina at kristina@elemed.eu to arrange a confidential career discussion.