MANAGER REGULATORY AFFAIRS DIGITAL

elemed

SOLOTHURN, SWITZERLAND

Get in touch with Tamanna at tamanna@elemed.eu

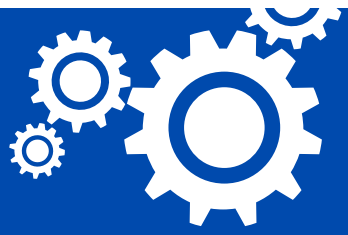
THE COMPANY

This is a great chance to join a leading Swiss Medtech company, with offices near Bern and Solothurn. This company has a very strong R&D group, which means the opportunity to work on bringing new innovation to the market globally. You will be part of a key strategic project initiative to bring software and hardware products to market faster and with an “agile approach”. This is a newly created role as Regulatory Affairs Manager with a key focus on digital and SAMD products.

THE OPPORTUNITY

This is a high level role, representing Regulatory on strategic company new product development projects and working across an innovative product portoflio. You'll be responsible for defining the regulatory strategy, as well as advising your partners on RA matters during the software development process. As this is a newly created role for the company, you'll also have the chance to implement the relevant tools, processes and documentation to ensure the company is meeting all regulatory requirements for Software and Hardware devices.

THE RESPONSIBILITIES



Some of your core responsibilities as regulatory affairs manager will include: (non exhaustive)

- Establish yourself as the key expert for all RA activities relating to software and hardware devices.
- Set, lead and implement the regulatory strategy for software as a medical device.
- Create processes and documentation within the company relating to software Regulatory requirements
- Train the engineering team on best practices regarding documentation and use of templates to standardize their documentation processes.
- Mentor the project team on how to conduct processes within the software system.
- Provide ongoing support, to ensure software quality is maintained during the product life cycle.

This is the chance to establish yourself as a senior RA expert and implement a new “agile” quality and regulatory approach in the company.

REQUIRED EXPERIENCE

Please apply if you have:

- Minimum 3+ years experience in the medical device industry
- Previous experience and expertise in bringing Software Medical Devices to market in a Regulatory role.
- We would also be open to profiles from a strong active medical device background.
- Strong knowledge of ISO 13485, MDD 93/42 And MDR (medical device regulation), IEC 62304 for Medical Software and IEC 60601 for Medical Electrical Equipment.
- Strong English communication skills. German would be a plus.

INTERESTED IN THIS POSITION?

Want to explore this further?

If you are interested in this exciting role, please send your application directly to tamanna@elemed.eu