Regulatory Affairs and Quality Assurance Manager (Senior)

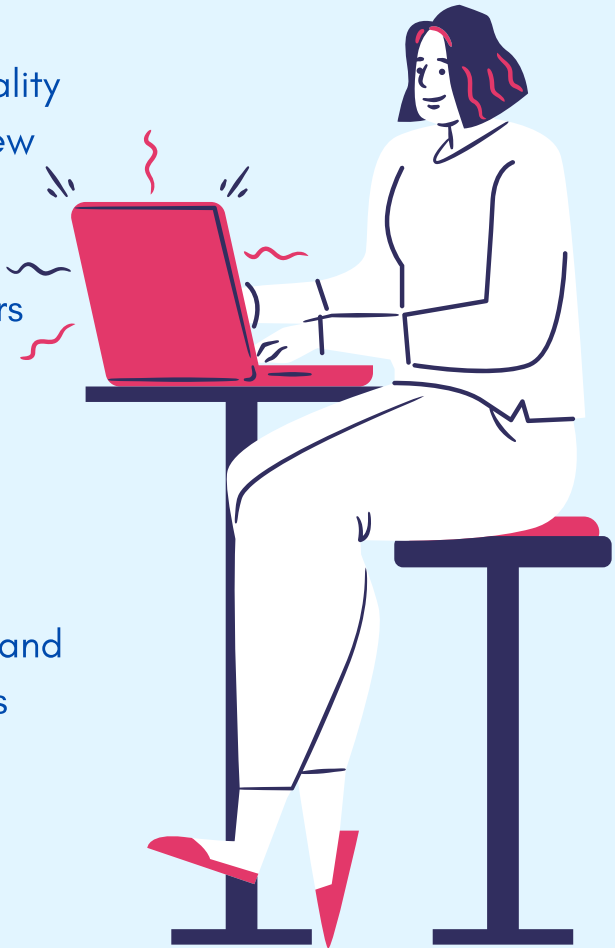
Solothurn / Bern, Switzerland

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 market globally.

As part of a key strategic project initiative to bring software and hardware products to market faster and with an “agile approach”, a new role has been created as Quality/Regulatory Manager with a focus on SAMD products.

This is a high level role, representing Quality and Regulatory on strategic company new product development projects. You’ll be responsible for defining the regulatory strategy, as well as advising your partners on QA/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.

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

- Establish yourself as the lead for all QA/RA activities relating to software and hardware devices
- Set, lead and implement the regulatory strategy for software as a medical device
- Defining the quality attributes associated with the output of Software projects and how those attributes should be assessed (Quality planning)
- Lead Quality assurance responsibilities: managing the design control process to ensure the quality of the software meets QA/RA requirements for the area of application
- Create processes and documentation within the company relating to software Quality and 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 such as quality reviews during the development process
- Support and ensure that the quality control team tests and reviews software at different stages to ensure a good quality assurance process
- Be sure that existing processes relating to changes and CAPA for/of SAMD are optimised and meet Quality and Regulatory requirements
- Provide ongoing support, to ensure software quality is maintained during the product life cycle

This is the chance to establish yourself as a senior QA/RA expert and implement a new "agile" quality approach in the company.

Please apply if you have:

- Minimum 7+ years experience in the medical device industry
- Previous experience and expertise in bringing Software Medical Devices to market in a Regulatory OR quality role
- 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 and good spoken German

elemed

We'd love to hear from you!

Please send your CV to elena@elemed.eu to arrange a confidential career discussion.

Only applicants who meet the requirements above will be considered for the role. Unless otherwise stated we are not able to consider applicants without EU work authorization.

Elemed is an executive search firm, specialized in finding and representing exceptional talent in medtech. To find out more about our Candidate Services visit: https://www.elemed.eu/candidates/