Senior Regulatory Affairs and Quality Assurance Specialist, Medical Software

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 Senior Quality/Regulatory specialist with a focus on software as a medical device (SAMD) and hardware devices.

This is a great role allowing you the opportunity to support development projects from a QA/RA perspective. You'll be responsible for implementing the regulatory strategy, as well as providing QA/RA input during the software development process.

As this is a newly created role for the company, you'll also have the chance to support the implementation of relevant tools, processes and documentation to ensure the company is meeting all requirements for Software and Hardware devices

Some of your core responsibilities as Senior QA/RA specialist will be: (non exhaustive)

- Support QA/RA activities relating to software and hardware medical devices
- Quality assurance: supporting 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
- Help the engineering team understand best practices regarding documentation and use of templates to standardize their documentation processes
- Participate in quality reviews during the development process.
- Support the quality control team with information required for tests and reviews of software at different stages to ensure a good quality assurance process
- Ensure that existing processes relating to changes and CAPA for/of SAMD are optimised and meet Quality and Regulatory requirements
- Provide ongoing QA/RA support, to ensure software quality is maintained during the product life cycle

This is the chance to really specialise on QA/RA for two really fast growing areas; software and hardware medical devices, and be part of a new "agile" quality approach in the company.

Please apply if you have:

- Minimum 2+ 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

We'd love to hear from you!

Please send your CV to paul@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 click here: https://www.elemed.eu/candidates/