

Senior Quality System Specialist

**St Gallen region– 40%
home office options**

tamanna@elemed.eu



The company

In this role, you will work for a mid-size medical device company, with a strong international presence in Switzerland, Germany, and China. This medical device manufacturer is the market leader in its field, enjoying strong partnerships with some of the world's most renowned MedTech companies, as well as designing and developing its own products. Owing to a dynamic acquisition strategy, this company has enjoyed fast-paced growth and is entering the next (exciting!) phase of its expansion journey. You will be working directly on their main manufacturing site allowing you to be at the heart of the action.

The opportunity

To support the growth of their Regulatory and Quality division, they are looking for an enthusiastic and proactive Senior Quality Systems Specialist to design and implement a QMS. You will also be second to the Head of Site, allowing you to develop key managerial responsibilities and skills.

In this position, you will be reporting directly to the Site Lead for RA/QA, with a dotted line to the VP of RA/Q allowing you to have the ability to build a crucial part of the business. This is a great opportunity to join a close-knit team in a hands-on role with an innovative and exciting product. You can be sure that no two days will be the same!



The responsibilities

As Senior Quality Systems Specialist you will...

- Support the development, maintenance, and improvement of the Quality Management System according to ISO 13485
- Be responsible to generate, review and edit SOPs, and other applicable documentation within the QMS responsibility
- Ensure compliance of all technical documentation according to ISO 13485
- Work cross-functionally with members of the medical and technical departments
- Interface between sales, development, and regulatory affairs to ensure that a high level of Quality is maintained across the business
- Play a critical role in the company's internal and external audits



Qualifications

As Senior Quality Systems Specialist you should have...

- Bachelor's OR Master's degree in relevant Engineering or related technical field or equivalent
- Minimum 3 years of experience in Quality Management/ Quality Assurance in the medical device industry
- Hands-on experience with ISO 13485
- Strong written and verbal communication skills in English AND German
- Some project management experience and the ambition to want to develop into a managerial role in the future

If you are interested in this exciting role, please send your application directly to

tamanna@elemed.eu

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