ST GALLEN, SWITZERLAND

(UNFORTUNATELY WE CANNOT CONSIDER CANDIDATES WHO ARE NOT WILLING TO BE BASED IN ST GALLEN FOR THIS ROLE)

Head of Site RA/QA

TAMANNA@ELEMED.EU

Scope of position

This exciting role is for a Site Quality and Regulatory Head, leading all quality activities for an important manufacturing site for the company, in its headquarters located in St Gallen.

This role reports to the overall Site Director, with a dotted line reporting to the Vice President for RA/QA. This is a strong leadership role where you'll be managing managers, and an overall department of approximately 40 people covering all areas of quality management and quality operations; quality control, quality assurance etc. This role will be highly visible across multiple functions: regulatory, operations, procurement etc, and the main liaison with regulators, Notified Bodies, and customers for all quality-related topics.

The Head of RA/QA is the Site Management representative to ISO 9001/13485 and the Person Responsible for regulatory compliance (PRRC) under EU MDR.

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.

The role

As Site Head of RA/QA, you'll have the responsibility to lead the team and company through the next exciting phase of its growth. You'll also ensure that the quality system is effectively established and maintained in line with ISO 9001 and ISO 13485, as well as oversee the technical and strategic management of the site from a quality leadership point of view. Finally, you'll have the ultimate responsibility of ensuring that the site maintains its ISO 13485 and ISO 9001 certifications.

The role

Are you passionate about leadership, mentorship, and building a strong culture of quality?

You will oversee both the quality operations and quality management system teams within the organisation, and help to contribute to their “culture of quality” transformation. You’ll be responsible for their development, hiring, training, mentoring, and performance management as well as acting as an advisor to other teams and departments on all quality-related activities.

In this role as Head of Regulatory/Quality, your activities will be both strategic and operational, we are looking for someone with a big-picture mindset, yet unafraid to roll up their sleeves and jump in when needed!

The responsibilities

- Translate company quality goals and direction from management into operating principles and tactics
- Be responsible for all the site quality processes and teams, such as quality control/acceptance activities, measuring and test equipment, process validation, CAPA, and more
- Lead, inspire, and drive teams to achieve their goals, problem-solving, removing roadblocks/ bottlenecks, and providing the group with technical expertise on quality and regulatory compliance topics
- Anticipate and communicate any quality issues/conflict to the SLT, partnering with stakeholders and proposing reasonable and compliant solutions
- Represent and advocate for safety, effectiveness, and quality, with a “quality as business partner” approach
- Inspire and promote a sound quality culture within the company
- Lead the organization in the development, implementation, and continuous improvement of a fully compliant Quality Management System (QMS); which is tailored to business needs and device risk

The responsibilities

- Lead and guide quality teams to deliver results in a timely manner; able to roll up sleeves and get “hands-on” when needed
- Work with key partners within the organization, providing strategic direction and support where needed, especially on the topic of quality management and quality operations
- Be responsible for educating other partners and employees from the company’s business units on topics regarding quality, to build a culture of quality across all levels and functions of the organisation
- Build a trustworthy and cooperative relationship with the other functions within the company (e.g. OPS, R&D, Purchasing..)
- Lead and be the face of the company for external audits e.g Notified Body, customers, etc
- Department budget and cost controlling
- Mastering all quality topics, assessing risks, and managing priorities, according to business needs
- Ensuring that complaints are managed properly and in a timely manner and that corrective actions are implemented as needed
- Monitor product compliance tracking and related projects
- Strong communication skills and ability to influence would be well received in this role

Are you motivated by having the chance to make improvements?

Do you find innovative ways to solve problems?

Do you see challenges as problems or opportunities?

Requirements

Applicants must meet the following:

- 9+ years experience in a quality role in the medical device industry
- 5+ years experience in the management of teams within quality
- Strong experience with quality management systems ISO 13485, AND quality operations
- Fluent in German and English
- Confidence and ability to make independent decisions based on sound principles
- Experience with ISO13485, ISO 9001, ISO14971 and relevant regulatory standards i.e MDD 93/42/EEC
- Ability to influence through communication
- Able to work on-site 100% in St Gallen

Get in touch

INTERESTED IN FURTHER CONVERSATION?

IF YOU ARE INTERESTED IN THIS EXCITING ROLE, PLEASE SEND YOUR APPLICATION DIRECTLY TO:

TAMANNA@ELEMED.EU

Would you like to find out more about our open opportunities? Visit https://www.elemed.eu/vacancies/