ST GALLEN, SWITZERLAND

Director of Quality

Quality Management Systems and Quality Operations for a major site

Scope of position

Site Quality Director, leading all quality activities at 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 functional leader for global QM/RA. This is a strong leadership role where you'll be managing managers and an overall department of approximately 30 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 Quality Director is the Site Management representative for 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 Quality Director, you'll have a 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.

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 advisor to other teams and departments on all quality related activities.

In this role as Director of 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!

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,...
- Lead, inspire and and drive teams to achieve their goals by 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
- Lead and guide quality teams to deliver results in a timely manner; be able to roll up sleeves and get “hands on” when needed!

Responsibilities

- 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

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Requirements

- 9+ years experience in a quality role in the medical device industry
- 5+ years experience in double layer management; managing managers
- Strong experience with Quality Management Systems ISO 13485 and quality operations
- Fluent 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

Interested in further conversation?

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