Vice President Quality EMEA

ZUG, SWITZERLAND

The Opportunity

This is a rare opportunity to head a major region and function for one of the medical device multinational heavyweights. If you are looking for a position with top-level company exposure, autonomy and accountability, this could be a great career move for you. Only a handful of companies can offer roles of competing size and scope in Europe at this level, and this is one of them.

The company is a world leader in its field, where the idea of “quality and safety” forms part of its core values. Internally, quality is a highly respected and prominent function within this organization.

The role

This is a role with an extensive scope. The Vice President Quality EMEA will have oversight of 8 multi-divisional and multi-geographical sites (comprising class III implants, software, electromedical devices, tools & more). You’ll lead a department of around 400 employees across EMEA with diverse backgrounds and cultures and direct the quality strategy for the region.

You will be the decision-maker for Quality related matters for EMEA, so this position would appeal to a candidate who is able to make complex risk-based decisions balanced with business needs. As the company grows, your challenge will be to focus on quality excellence and systems improvement across the organization.

The role

- You will have responsibility to ensure that the global business and quality system goals and objectives are met for all locations in your remit.
- Develop, drive and implement the quality strategy throughout the region
- Operate multi divisional quality control, quality assurance, quality audits and regulatory compliance activities and strategies.
- Drive the planning and implementation of quality plans throughout EMEA
- Ensure effective and timely implementation of quality systems (complaints, CAPA, process validations, training, field actions, design assurance)
- Act as respected representative for interactions and collaborations with corporate QA/RA functions to share and/or implement global quality system standardization and/or sharing of best practices
- Work to ensure successful maintaining of ISO 13485 certifications and compliance to FDA QSR
- Develop close collaborative working relationships with other EMEA leadership partners (e.g. R&D, Operations, HR, Sales, Marketing and Finance)
- Anticipate and plans for future regulatory changes and impact on business success
- Drive the decision-making process involving QC/QA/regulatory compliance
- Communicate company-wide policies on quality and regulatory compliance issues effectively
- Manage a large budgetary responsibility. Plans, execute, and update budgets
- Develop and champion and organizational culture that promotes behaviors leading to superior business performance and optimized regulatory compliance.
- Ensure QARA employees are being developed and empowered and leadership pipelines are adequately staffed.

Expectations:

We are looking for seasoned professionals with a proven background in medical device quality operations and leadership:

- 15+ years experience working in a quality operations role within the medical device industry and mastery of the relevant standards: ISO 14971, ISO 13485, EU regulations, quality and regulatory compliance processes, QSR/GMP, reporting etc.
- 10+ years experience in leadership, managing managers or directors.
- Ability to delegate, strategize and empower your team.
- Previous experience working in and ability to navigate a corporate matrix environment
- Fluency in English AND one other European language (Fluency in German/French is highly beneficial)
- Proven track record of multi-site management (minimum of 3 sites), located in different countries.
- Deep understanding of manufacturing quality processes i.e operational quality, technology transfer (R&D to manufacturing).
- Experienced at managing recalls, FDA interactions, , inspections and audits and strong aptitude for using knowledge of regulatory and quality to solve operational compliance issues

INTERESTED TO EXPLORE THIS FURTHER?

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