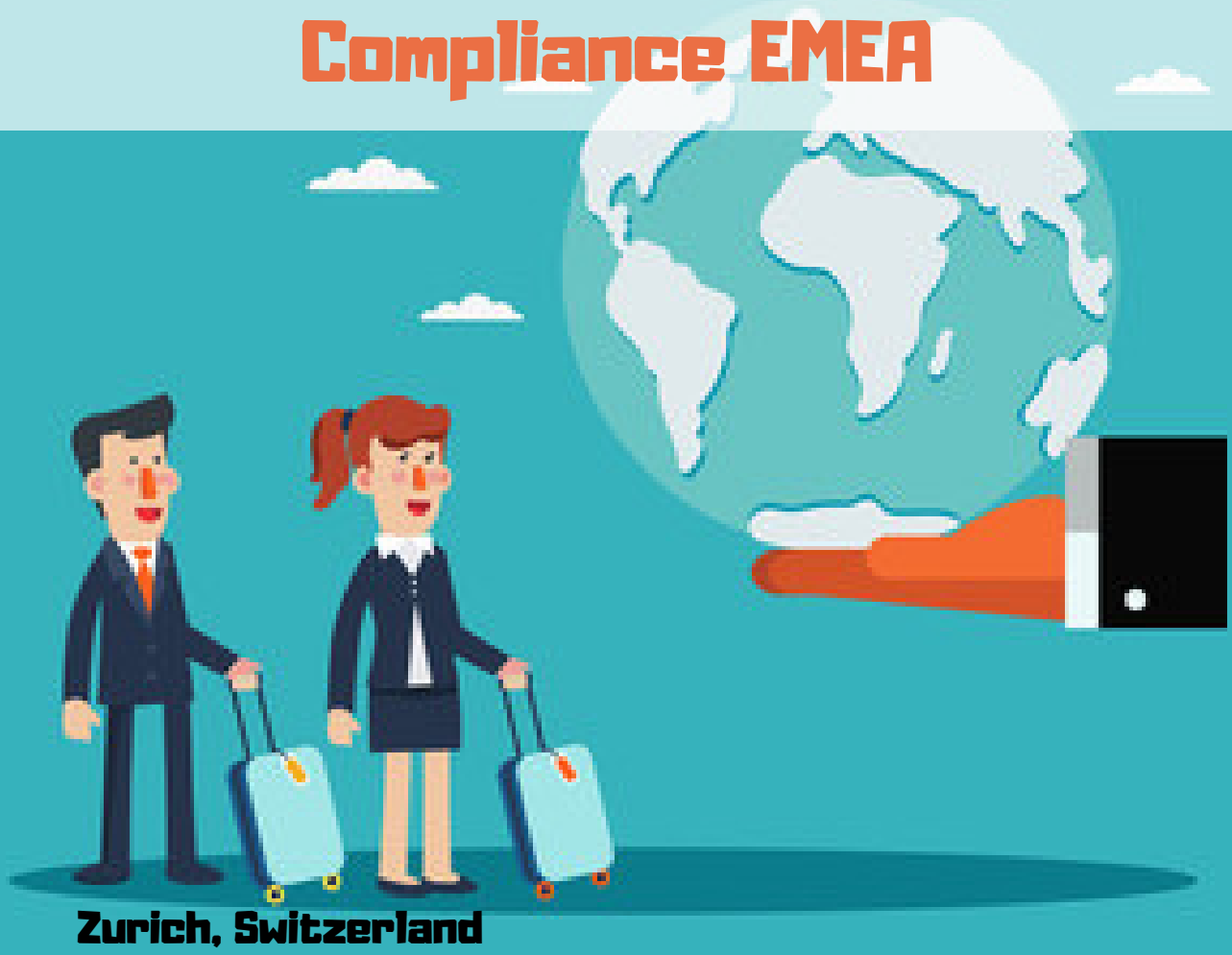
VP Quality & Regulatory Compliance EMEA



Zurich, Switzerland

THE OPPORTUNITY

This is a rare opportunity to head a major region and function for one of the medical device heavyweights of class III devices. 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, and as such, quality as a whole doesn't report to a COO or CMO but straight to the CEO.

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, processvalidations, 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.

Essential Requirements:

- 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.

We'd love to hear from you!
Please send your CV to hello@elemed.eu
to arrange
a confidential career discussion.