

HEAD OF QUALITY

Zurich, Switzerland



THE OPPORTUNITY

IF YOU ARE LOOKING FOR STABILITY AND CAREER GROWTH, LOOK NO FURTHER. JOIN A SWISS MEDICAL DEVICE & DIAGNOSTICS COMPANY PLAYING ON THE GLOBAL STAGE. WITH A STRONG EMPHASIS ON PROFESSIONAL EMPLOYEE DEVELOPMENT (THEY HAVE THEIR OWN INTERNAL TRAINING PROGRAM), YOU CAN BE SURE THAT THIS WILL NOT BE A STATIC ROLE.

THE COMPANY HAS A REPUTATION OF HAVING A 'CULTURE OF QUALITY' WHICH IS RECOGNIZED BOTH INTERNALLY WITHIN THE ORGANIZATION (QUALITY IS SEEN AS A PARTNER, NOT A POLICEMAN), AND EXTERNALLY (4 CONSECUTIVE FDA INSPECTIONS WITH 0 FINDINGS). THIS IS A COMPANY GROWING, BOTH ORGANICALLY AND STRATEGICALLY BY ACQUISITION, ITS SHARES ARE OVER-PERFORMING, AND IT IS SOON TO BE THE MARKET LEADER IN ITS SPACE. FROM A QUALITY PERSPECTIVE, THE STANDARD IS HIGH; ALL SITES ARE SWITCHED ALREADY TO ISO 13485:2016 AND IT HAS RECENTLY PASSED THE MDSAP AUDIT. 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 CHALLENGE:

So what's the challenge? To make something good even better!

The Head of quality will report to the Senior Vice President Quality & Regulatory and will have complete quality oversight of the company's biggest and most important site, located in the Headquarters of Zurich, where there are around 500 people.

This role will also have responsibility for a small site in Germany. Along with all classic quality responsibilities, this person will also have the unique opportunity to come up with their own ideas for implementing quality improvement projects with a view to achieving excellence in the organization.

THE ROLE:

Because this role is located in the company HQ, where the senior management team, board and the CEO sit, this role will have significant interaction and exposure to the company's Leadership Team. We are looking for dynamic, seasoned Quality professionals with experience in operations and stakeholder management who are able to influence both up and down reporting lines.

>>> Swipe up

- **Lead the quality organization of Switzerland and Germany in line with the Company's Vision and Values of Ambition, High standards and Trust**
- **Drive compliance of both products and processes to applicable standards and regulations globally (e.g. QSR, ISO 13485)**
- **Have responsibility for all Quality aspects relating to products and processes manufactured in Switzerland and Germany**
- **Have a commercially minded approach to quality to support the business achieve its goals and objectives**
- **Drive projects to improve the reliability and quality of products by establishing effective control mechanism in operations and supplier management**
- **Organize, prepare and participate to internal, 3rd party and supplier audits**
- **Interface to customers regarding quality topics as an OEM supplier and ensure that the customer's expectations are managed and met**
- **Ensure continuous improvement across the organisation**
- **Drive accountability towards effectiveness of the QMS**
- **Support and execution of risk management activities related to the scope of work (products, processes, complaints, NCR's, CAPA's,)**
- **Creation of Quality documentation related to products and processes in German and English**
- **Manage the budget for own cost centres**



EXPECTATIONS:

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

- 10+ 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.**
- 8+ years experience in leadership and quality operations**
- Strong stakeholder management and assertiveness**
- Fluency in English AND German**
- Previous experience with FDA inspections**
- Proven experience with manufacturing quality processes, operational quality, Quality Systems Management, Audits, Quality Engineering**

WE'D LOVE TO HEAR FROM YOU! PLEASE SEND YOUR CV TO ELENA@ELEMED.EU TO ARRANGE A CONFIDENTIAL CAREER DISCUSSION.