GLOBAL HEAD QUALITY AND REGULATORY AFFAIRS

LEIPZIG AREA

hello@elemed.eu

THE COMPANY

This fast growing company of 200+ people is a leader in developing and delivering high-tech class III cardio devices and accessories to over 80 countries across the globe. With high standards and dedication to quality, patient-safety, innovation and outcomes, they have been growing very rapidly over the last few years and have a promising pipeline growth for the future. This is a great time to join and have a real impact on shaping the QA/RA strategy in MDSAP, MDR and future new market approvals.

We are looking for someone who has a strong sense of leadership to manage teams across three international sites and have a good understanding of the impact QA/RA can have on the overall company. As Global Head QARA you will report directly to the senior leadership team (COO) giving you the ability to “speak to the business” and really influence the future of the quality/regulatory department in the company.

As Global Head Quality and Regulatory Affairs you will:

- Lead and coach a team of around 30 across 3 different sites locally and internationally
- Manage, synthesize and optimise the current Quality Management System and support the transition to an eQMS
- Establish and implement a company wide strategy for the transition to the new MDR
- Shape registration strategies for international markets including 510(k), IDE, PMA
- Devise budgets and plans for CE marking strategies
- Coordinate all RA/QA related activities

>>>Swipe to read about responsibilities

Requirements:

- 9+ years RA/QA experience in the medical device field
- 5+ years people management experience
- Previous experience working with Class III medical devices
- Fluent written and spoken English
- Willingness and availability for 60%+ European travel

For a confidential discussion; please send your CV to hello@elemed.eu