

# CQRO - CHIEF QUALITY / REGULATORY OFFICER

**NORTH LONDON AREA  
(RELOCATION OFFERED FOR EXCEPTIONAL CANDIDATES)**

## What we love

- Strong purpose and ethics
- Very broad product portfolio, highly innovative company
- Global focussed role covering everything in Q/RA
- Reporting to CEO
- Part of SLT
- Building culture of quality, with top level support
- Strategic and hands on role
- 100% privately owned, no shareholder pressure, red tape or politics
- Retirement replacement with handover
- Chance to be part of a growth story
- 200% growth achieved in 2020

## The Opportunity

Does “culture of quality” mean something for you? How about the chance to create a culture of quality for a company? Want something that is already perfect, and corporate?

This is not the role for you. This mid-size healthcare company’s mission is all about saving lives through infection prevention. Due to the COVID pandemic, they are in the heart of explosive and unprecedented 200% growth since 2019. Now they have an ambitious 5 year plan to become a world leader, and are looking to recruit its Chief Quality Regulatory Officer to help reach their goals.

You’ll report to the CEO and co-founder, giving you direct access to the top level, as a culture of quality starts at the top. Quality and reputation is something the owners believe in passionately, the goal of this role is all about ensuring Quality is not a department, but a culture that is lived and breathed by the whole company, as they go through significant growth to become a world leader.

The initiative, led by the company's CEO, is a one of a kind opportunity for a well-established Senior Director-VP Quality/Regulatory - who is open to the challenge of stepping up and having a real impact. This is a role with a high level of exposure and accountability. It's fast paced, decisions are made quickly, your role is working on global strategy, and there will be times where you'll roll up your sleeves and get close to the detail.

The company is privately owned with no outside investment, making it extremely stable. It's a great time to join if you're interested in a company with minimal politics and red tape. This is a role where your voice will be heard and listened to, you will have a seat at the SLT table. The company is the perfect size to be able to have an impact and influence change at around 250 people globally.

## In your role as Chief Quality and Regulatory Officer you will:

- Support the company's Growth plans through entering and expanding new markets internationally as well as supporting New Product Introductions covering a broad product range; medical devices, biocides, pharmaceutical and capital equipment.
- Drive and build a culture of quality within the organisation through strong strategic partnering with business and commercial functions.
- Define the Quality / Regulatory strategy globally for the company in order to enable the business to achieve its growth plans
- Represent the Quality and Regulatory function on the global leadership team, working with internal and external partners to ensure business objectives are met
- Drive the whole Quality and Regulatory organisation and budget globally (approx. 20 people internationally), coaching, mentoring, empowering and motivating your group.
- Prepare the organisation for current and future challenges relating to Regulatory/Quality; MDR, ISO13485, and oversee the global QMS implementation
- Oversee regulatory filing, agency interactions and the full product lifecycle from development, product approval, manufacturing, post market activities.
- Manage the Quality Management organisation, ensuring quality policy,
- internal audits, training and monitoring of quality objectives are met.
- Develop close collaborative working relationships with other leadership partners (e.g. R&D, Operations, HR, Sales, Marketing and Finance)



- Anticipate and plan for future regulatory changes and impact on business success
- Communicate company-wide policies on quality and regulatory compliance issues effectively
- Ensure QARA employees are being developed and empowered and leadership pipelines are adequately staffed.

## Expectations

- Technical / scientific university degree
- 15+ years experience in Quality/Regulatory roles in the medical device industry
- Global QA/RA experience
- 10+ years managing teams locally and remotely
- True “leadership” skills. Ability to influence indirectly, winner of hearts and minds
- Commercial understanding of how QA/RA is a business enabler
- Proven experience of building and embedding strong culture of quality within an organisation

## Interested to explore this further?

Please send your CV to [elena@elemed.eu](mailto:elena@elemed.eu) to arrange a confidential career discussion. Interviews have already begun. Elemed is a executive search firm, specialized in finding and representing exceptional talent in medtech.



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