



GLOBAL QA EXCELLENCE MANAGER

Home-based in Europe

Are you passionate about global Quality Excellence for medical devices? Are you an expert in Quality processes, systems and CSV? Have you got a curious mind that you want the freedom to explore with the support of your company? Read on!

THE COMPANY

This company has been enhancing performance in healthcare across the world for over 150 years so have a huge amount of history behind it including being the first company to mass-produce dressings for wound care. Even though they have developed and manufactured many revolutionary devices, the innovation doesn't stop and is done in-house!

They are always looking for new ways to improve not just in what they produce but also how they do business so have recently undergone a huge business transformation.

The value of work-life balance is strongly recognised here so, even though the headquarters are based in Sweden, this opportunity is open to be based from home anywhere in Europe. If you are looking for a large, established company that still feels like family, this is the place for you!

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THE OPPORTUNITY

This is an opportunity to be responsible for QA Excellence across the business globally. As the glue between different departments, you will guide and steer corporate-wide decisions to improve the effectiveness and efficiency of QA processes and systems throughout the organisation.

You will be responsible for developing and monitoring meaningful KPIs to measure QA process performance as well as identifying improvement areas, devising and implementing solutions by influencing key stakeholders/teams, prioritise resources/projects and ensure CSV compliance. It's not often that you have the opportunity to transform and influence quality in such a large, established organisation...

If you want to explore your curiosity with the support of your company, have a passion for Quality Excellence, and have experience in CSV, this is just the position for you!

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THE RESPONSIBILITIES

As Global QA Excellence Manager you will (not an exhaustive list):

- Create, monitor, and report on relevant KPIs to measure quality performance
- Assess process management maturity within QA
- Identify QA improvement areas, develop, and implement solutions in collaboration with the Quality Leadership team and other departments
- Implement new, enhance and improve existing IT tools, and ensure software CSV compliance
- Prioritise resources and quality projects in agreements with the involved departments/teams
- Work with QA and interface with partners to share best practices and transfer knowledge
- Support global standardization of QA processes
- Act as QA subject matter expert, supporting projects and project managers, direct questions to functional or process SME

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YOUR QUALIFICATIONS

- 5+ years of quality assurance experience in the medical device industry
- Demonstrated working experience on ISO 13485, MDR, and FDA 21 CFR part 820 / part 11 / part 211, cGMP, and CSV
- Lead groups of people during projects
- Eligibility to live and work in Europe

Interested to explore this further?

If you are interested in this exciting role, please send your application directly to kristina@elemed.eu