QUALITY SITE DIRECTOR

South of France

elena@elemed.eu

THE COMPANY

- Are you passionate about Quality, and quality culture change?
- Do you have excellent interpersonal skills and cultural awareness?
- Are you someone who is committed to delivering results?

If nothing changes, nothing will change.

This is your chance to join one of the world's top players in the medical device industry and bring about a real quality culture transformation. If you are looking for a role that will allow you to maintain the status quo, this isn't one for you. Apply for this role if you're looking for a chance to make a mark and see the direct impact of your actions.

THE COMPANY

We are looking for a quality leader to drive all quality activities for a recently acquired site, and manage a group of 43 quality professionals, building strong relationships with the site's operation and R&D director, as well as being the liaison between the US and France.

Robotics - You'll be joining one of the most dynamic and growing divisions of this top 20 Medtech manufacturer. This site has extra attention from the company's executive leadership team due to its strategic importance.

Reporting to the VP QA/RA in the USA, you will lead all quality for the whole site and the integration project for this site and its suppliers, bringing performance up to the corporate standard, within a matrix structure.

THE OPPORTUNITY

As site Quality director, you will lead a department of 43 people across: Quality systems, Doc Control, Design quality, Supplier Quality, and Validation.

You'll be part of the site's leadership team.

And you'll be based in the beautiful South of France, so you will have the chance to enjoy, lots of Sun, Sea and... a Super Quality team.

YOUR RESPONSIBILITIES:

- Take the lead in developing the "Quality Spirit" within the company
- Be responsible for ensuring the site is compliant with all relevant regulations and standards: ISO 13485, CFR21Part 820, Sors 98282, Directive 93/42/EEC, MDR
- Implement and evolve the QMS in line with the Quality policy from corporate, and manage all quality documents. Report to the company's top management on opportunities for improvement within the QMS
- Be in charge of QA budgets and ensure that QA actions are aligned with the company's overall strategy, enabling continuous quality improvement
- As part of the management team, develop the operating objectives of the QA
- Develop and define performance objectives for the Quality function. As Quality director, you'll have the authority and responsibility to ensure quality objectives and their achievement. Prioritizes QA function objectives to meet deadlines

YOUR RESPONSIBILITIES:

- Responsible for communications with Notified Bodies or competent authorities
- Lead, motivate and develop capability within the Quality team
- Responsible for the implementation of changes to procedures, processes, and design
- Draws up the certificates of conformity of the final products
- Systematically Analyse Non-conformities and selected customer complaint investigations with regards to risk and material vigilance and communicate findings to the impacted organizations
- Assess quality-related issues: be technically competent to evaluate validation activities and data to ensure that design control/validation activities and data are properly implemented and used to support desired objections and conclusions.
- Define the appropriate procedures and measures for each process to meet customer expectations by adhering to quality standards

YOUR QUALIFICATIONS:

- Experience in a quality role in medical devices, in a multinational matrix company
- Management experience (double layer managing managers)
- Experienced in Leading audits/inspections (front of house) FDA or EMEA
- Strong motivation and commitment to driving results
- Fluent in French and English

INTERESTED TO EXPLORE THIS FURTHER?

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

Would you like to find out more about our open opportunities? Visit https://www.elemed.eu/vacancies/

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