CAPA ENGINEER

Verona, Italy

THE COMPANY

Are you looking to join a growing medical device company where you will play a critical role within their Quality department?

Since its founding over 40 years ago, the company has enjoyed a proud history of successes by providing surgeons and patients with innovative solutions in the field of active and implantable medical devices, thanks to a collaborative environment dedicated to developing, manufacturing, and distributing diverse product lines in more than 60 countries worldwide.

Do you love collaborative environments? The company really values its employees and supports them to continuously develop and grow.

This is a fantastic opportunity to work in a multinational company engaging with different teams across Italy, the UK, and the US. As the CAPA Engineer, you will be based in Verona (Italy), the heart of the manufacturing site, reporting directly to the Quality Compliance Manager.

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THE OPPORTUNITY

This is an opportunity with high exposure to senior leadership, a chance to share your ideas and be heard by the business.

You would be joining a small team where you will play a huge part in the improvement of the company's status quo and leave your mark.

It is a very dynamic role with a variety of activities and tasks, so it's unlikely that you would get bored!

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THE RESPONSIBILITIES

- Supporting the maintenance and improvement of the QMS processes
- Establishing and driving strategies to achieve quality compliance standards related to the CAPA
- Supporting a team of qualified investigators in carrying out analysis and removal of root causes
- Reviewing CAPA investigations performed by the Quality team to ensure that documents are thoroughly completed in a timely manner
- Establishing training material for the CAPA program and ensuring it maximizes performance and its compliance with worldwide regulatory requirements
- Leading the CAPA Review Board (CRB) process
- Verifying the product safety and efficacy has been evaluated and issues are elevated for risk evaluation

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THE RESPONSIBILITIES

- Ensuring the metrics are identified, compiled, and reviewed in order to identify adverse trends and their drivers
- Working closely with Senior Management and Quality Compliance team to ensure a responsive, efficient, and effective service
- Authorizing changes to CAPA Management Systems.
- Primary CAPA system contact during regulatory inspections and Corporate AQR audits
- Reviewing and evaluating processes and work products, recommending improvements
- Supporting QA to collect, evaluate and analyze quality records, reporting periodically to senior management corrective and preventive actions

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YOUR QUALIFICATIONS

- Minimum 3 years of experience in Quality for medical devices. CAPA management experience is a bonus
- Scientific mindset, great communication skills
- Fluent English

INTERESTED TO EXPLORE THIS FURTHER?

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

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