ONSITE IN VERONA, ITALY (SOME HOME-OFFICE FLEXIBILITY) OR REMOTE IN GERMANY, UNITED KINGDOM OR FRANCE

Senior Quality Engineer

VERONICA@ELEMED.EU

The company

Are you looking to join a company committed to delivering innovative, quality-driven solutions to meet the needs of their patients?

Since its founding over 40 years ago, this company has enjoyed a proud history of success by providing surgeons and patients with innovative solutions and new products such as its active implantable medical device. It is passionate about improving patients' lives and is driven by its culture of integrity. All of this is thanks to its collaborative environment dedicated to developing, manufacturing, and distributing diverse product lines in more than 60 countries worldwide.

If you are ready to make a difference and have a purposeful career, this is the right opportunity for you!

Its global team is empowered to make a difference in the Active Implantable Medical Device field through work, volunteer activities, charitable giving, and employee programs as their success is built on the efforts of people.

The opportunity

This is a great opportunity to join a global team of dedicated professionals at an exciting point of its growth, with a culture built around integrity, respect, fun, and engaging with international teams from Italy, France, Germany, the UK, and the US!

As a Senior Quality Engineer, you will support product development activities, ensuring compliance with the product standards, regulations, and Quality System requirements.

You will have the chance to bring your skills and experience with electric medical devices or Software as a Medical Device, and really be the subject matter expert in the team. You will also be liaising with all the different departments from R&D to Regulatory Affairs as the key point of contact for the Design Assurance during the design and development of new products.

Your responsibilities

- Maintenance of the existing validations according to the requirements
- Organization and coordination of internal and external testing activities
- Development of validation test plans, protocols, reports, and summaries
- Supervise the Risk Management activities, in relation to product modifications and during PMS
- Manage in cooperation with R&D, Marketing, Medical Science, and Clinical Affairs, the design validation of new products
- Prepare and maintain the Technical File documentation for new products or modified products and cooperate with the Regulatory Affairs team to prepare regulatory submissions

Your responsibilities

- Cooperate with other departments to achieve CE marking/FDA approvals for new products and product modifications

- Direct all the regulatory pre- and post-market activities related to technical aspects

- Support the R&D area to formalize the development plan, the development phase gate documentation, the design verification documentation, and the design validation

- Implement and update internal procedures relevant to the previously mentioned activities

- Conduct internal audits

- Plan the preparation and review of relevant product technical and marketing sheets, or ad hoc technical documentation requested to ensure continuity of product supply to the market

Qualifications

- 4+ years of experience in Quality OR R&D for Active Medical Devices or Software Medical Devices
- Fluent English
- Must be based in Italy, Germany, France, or the UK

INTERESTED IN FURTHER CONVERSATION?

IF YOU ARE INTERESTED IN THIS EXCITING ROLE, PLEASE SEND YOUR APPLICATION DIRECTLY TO:

VERONICA@ELEMED.EU