VERONA, ITALY

Design Quality Engineer (Active MD)

VERONICA@ELEMED.EU

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, this company has enjoyed a proud history of success by providing surgeons and patients with innovative solutions in the field of active and implantable medical devices. All of this is thanks to its 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.

The opportunity

This is a fantastic opportunity to work in a multinational company engaging with different teams across Italy, the UK, and the US.

As the Design Quality Engineer, you will be based in Verona (Italy), the heart of the manufacturing site, reporting directly to the Quality Engineering Manager.

You will 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 and you'll be the main person specialising in active medical devices.

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 post-marketing surveillance

- 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

- Minimum 3 years of experience in Quality for medical devices. Design assurance experience and experience with active medical devices is a bonus

- Scientific mindset, great communication skills

- Fluent Italian and English

INTERESTED IN FURTHER CONVERSATION?

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

VERONICA@ELEMED.EU