Regulatory and Quality Director

Nantes, France

monia@elemed.eu

The company

Join a well French established, start-up company specializing in the development of next-generation robotic solutions for medical devices that will change the lives of patients.

If you are looking for a role with a large team to manage, this position is not for you. But if you want to develop your own team this role will be perfect! This role is all about being hands-on with the product and working in a tight-knit team with one vision, surrounded by other senior experts in their field.

The opportunity

Under the responsibility of the R&D Director, you will ensure the monitoring compliance with the regulatory requirements specific to the electro-medical equipment that they design, manufacture and market.

Responsibilities

- Ensure the technical documentation and the EU declaration of conformity are drawn up and kept up to date
- Write design verification and validation protocols and reports
- Write process qualification & validation protocols and reports
- Pilot the process of risk management and suitability for use
- Support of the R&D team for the determination of the design input data
- Ensure the application of the standards and regulations in force for each project
- Organize tests carried out by external laboratories
- Compile the regulatory certification application files.
- Ensure that the processes necessary for quality management are documented
- Report to management on the effectiveness of the quality management system and any need for improvement
- Manage and perform internal audits
- Ensure that awareness of applicable regulatory requirements and quality management system requirements is promoted throughout the organization
- Ensure the conformity of the devices is properly verified, in accordance with the quality management system under which the devices concerned are manufactured, before the release of a device
- Ensure PMS obligations are fulfilled
- Manage CAPAs activities
- Define, manage and animate the Quality Management System
- Ensure product compliance and safety throughout its life cycle
- Manage non-conformities and corrective and improvement actions
- Be the company's contact with the notified bodies

- Ensure product compliance and safety throughout its life cycle
- Manage non-conformities and corrective and improvement actions
- Be the company's contact with the notified bodies

Your qualifications

- Minimum of 5 years experience in the medical industry
- Fluency in written and spoken English and French is essential
- Graduate Engineer Bac +5 minimum, generalist or with a scientific or technical specialty

Interested in this position?

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