Innovations made in France

Director of Quality Assurance and Regulatory Affairs

Working Hours: Daily Package

We, **E-Swin/ESW Vision Group**, are a French company from the Paris region, with our Marketing & Export Office in Linz and sales offices worldwide. Since 2008, E-Swin/ESW Vision Group stands for the development and production of innovative medical devices for the optical, ophthalmologic and aesthetic field.
At the office in France we are looking for qualified individuals who can contribute to ensuring the quality and regulatory compliance of our products.

TASKS

General Tasks:

- Responsible for QMS and regulatory affairs
- Management representative (representative of general management for ISO13485)
- PRRC (Person Responsible for Regulatory Compliance) in accordance with MDR2017/745 requirements.

Main Tasks:

- Quality management system compliance
- Support quality activities and decisions
- Monitoring of regulatory affairs requirements: certifications, vigilance, plans with certification bodies, local regulatory representatives, competent national authorities

The management representative (in accordance with ISO13485, paragraph 5.5.2) has the following responsibility and authority:

a) ensure that the processes required for the quality management system are documented:

b) report to top management on the effectiveness of the quality management system and any need for improvement;

c) promote awareness of applicable regulatory and quality management system requirements throughout the organization

The PRRC is responsible for ensuring that:

a) the conformity of devices is appropriately verified, in accordance with the quality management system under which the devices are manufactured, before a device is placed on the market ;

b) technical documentation and the EU declaration of conformity are drawn up and kept up to date;

c) post-marketing surveillance obligations are met (in accordance with Article 10, paragraph 10)

d) notification obligations are fulfilled:

- Actions on serious incidents and corrective measures relating to safety in the field
- Report on trends.
- Analysis of serious incidents and corrective safety actions in the field.
- Analysis of vigilance data.

SKILLS AND KNOW-HOW REQUIRED

- Knowledge of professional oral and written communication techniques
- Ability to use English in a professional environment
- Knowledge of office automation tools (word processing, spreadsheet, presentation and simple databases)
- Ability to implement techniques for organizing one's own work (space, time) and/or that of a team
- Ability to lead a team of colleagues
- Knowledge of control and audit methods
- Knowledge of the impact and challenges of updating information, ability to analyze and optimize circuits
- Knowledge of team management and reporting
- Engineering or scientific degree
- At least 3 years' experience in industry, preferably in the field of medical devices (ISO13485 certified)
- Experience as a PRRC (EU MDR 2017/745) and ISO13485 internal auditor would be a plus.
- English: very good essentials

OUR OFFER

We offer you the opportunity to contribute independently in a dynamic, international work environment. As the Quality Assurance and Regulatory Affairs Director, you will become an integral part of a dedicated team, with the chance to significantly shape and enhance the quality and regulatory activities within our company. Your role will involve actively contributing to the development and molding of our quality assurance and regulatory affairs strategies.

In this position, you will be offered an open-ended contract (CDI) with . The annual salary for this role is a minimum of €55-70,000 gross depending on profile and experience.

Have we aroused your interest? Then please send us your complete application documents by email to: **contact@e-swin.com**

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