



# Innovations made in France

## Quality Assurance and Regulatory Affairs Manager QARA

Working Hours: 35h



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:

- Undertake, under the authority of Management, any action with E-SWIN departments to ensure that the quality management system described in the Quality Manual is: implemented, monitored and improved
- Compliant with standards and the defined quality documentation system
- Support our partners and monitor international product registrations, ensuring compliance with national and international regulations applicable to E-SWIN and its products.

#### Quality Assurance:

- Participate in the implementation of quality policy and objectives
- Raise quality awareness among all staff
- Draft and update all quality system documentation
- Coordinate and monitor improvement actions (preventive and corrective actions, following audits (internal and external), following non-conformities), after analyzing the causes of non-conformities.
- Identify and update E-SWIN processes, and assist process managers in monitoring processes (objectives, indicators, improvement actions).
- Plan and carry out internal audits.
- Participate in management reviews.
- Improve the quality system
- Monitor standards and regulations

#### Regulatory Affairs:

- Analyze and apply the various regulations applicable to E-SWIN and its products.
- Work in collaboration with our partners abroad
- Provide required documents
- Monitor certification progress
- Prepare audits



### SKILLS AND KNOW-HOW REQUIRED

- Knowledge of professional oral and written communication techniques
- Ability to use written English in a professional environment: translation of documents (procedures, letters, e-mails)
- Knowledge of office automation tools (word processing, spreadsheets, presentation and simple databases)
- Ability to apply work organization techniques (space, time)
- Knowledge of control and audit methods
- Knowledge of the impacts and challenges of updating information, ability to analyze and optimize circuits
- Experience: 3 years
- Demonstrate rigor and precision
- Take initiative and make proposals
- Work as part of a team
- Education: Bac+3, Bac+4 or equivalent  
No field required Scientific background
- Languages: English, very good essential
- Qualification: Qualified employee
- Sector of activity: Manufacture of medical irradiation equipment, electro-medical and electro-therapeutic equipment

### OUR OFFER



We offer you the opportunity to contribute independently in a dynamic, international work environment. As the Quality Assurance and Regulatory Affairs Manager (QARA), 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 a standard working week of 35 hours. The annual salary for this role is a minimum of €42,000 gross.



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



E-SWIN SAS  
Rue des Côtes d'Orval  
ZA de la Prévoté  
78550 HOUDAN  
FRANCE



[www.e-swin.com](http://www.e-swin.com)