QRA Manager

Publication: Jan 22

Job Title	**QRA Manager**
Location	Grenoble, France
Start date	ASAP
Purpose	The role of the QRA manager is to ensure that the company is in compliance with all applicable standards and regulatory requirements.
contact	CV and presentation letter to recruitment@cardio-renal.com

Company overview

CardioRenal is developing TENOR, a Point of Care (POCT) device for measuring capillary potassium in patients with renal failure. This innovative device makes this measurement more reliable, which is generally highly degraded by the transport of the sample, particularly in rural areas. It empowers the patients in the monitoring of their own disease and the adaptation of their medical treatment.

Kidney failure now affects more than six million people in France and represents a budget of 4.5 billion euros for the healthcare system. Our ambition, by allowing more frequent and reliable monitoring of potassium, is to significantly reduce the number of hospital readmissions and thus improve the lives of these patients.

Key Responsibilities

• Management Representative

a) ensuring that processes needed for the QMS are defined, documented, implemented and effectively maintained

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

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

d) ensuring the training of the organization resources

• Responsible for the establishment of Technical Files and related Declaration of conformity

• Ensure Compliance of the device with the European Regulation (IVDR & MDR) and FDA 21 CFR

• Management of the quality management system ISO 13 485: 2016

• Responsible for the establishment and redaction of procedures, instructions and templates

• Responsible for Vigilance, post-market surveillance and implementation of Field Safety Notices (FSN)

• Responsible for the Regulatory Watch and the Establishment of Transition Plans as required

• Ensure the treatment of discrepancies, identify the causes and implement appropriate corrective actions

Key Skills and Competencies

Education & Qualifications

- **Education**: Post-secondary and/or graduate education or equivalent experience Bac +5 – Trained to ISO 13485 : 2016, to medical device regulations. (Biomedical) Engineer background is a plus
- **Languages**: Fluent in English

Experience and competencies

- Experience in management of QMS ISO 13485 :2016 (+ 4 years)
- Knowledge of IVDR/746 regulation
- FDA 21 CFR experience or knowledge is a plus
- Experience about ***in vitro*** **diagnostic** and medical devices (+ 4 years)
  - ❑ Understanding in software device and self-test devices is a plus
- Experience from leading projects
- Excellent written and verbal communication skills
- Presentation skills
- Extensive Computer software package skills (Excel)

Personal Characteristics

- Structured mind
- Team player
- Problem solving skills
- Efficient and well organized
- Process oriented