

IVD product manager

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Job Title	IVD product manager
Location	Grenoble, France
Start date	ASAP
Purpose	Project sensor development from technical validation to market
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

- Manages the project's progress towards established goals, identifies, and communicates project risks that may affect the expected outcome.
- Gathers critical facts and data for the team to make decisions and adjustments to project direction, schedule, and resource allocation.
- Owner of specifications, risk analysis and manufacturing process files.
- Understands and follows the technical file compilation for certification of the device.
- Assures that the product requirements have been met through testing and analysis.
- Participates in validation activities.
- May participate in R&D activities.

Key Skills and Competencies

Education & Qualifications

- Education: Biomedical Engineering Degree
- Languages: Fluent in French and English

Experience and competencies

- Experience in the medical device or regulated environment (2-4 years)
- Project management
- Good written and verbal communication skills

Nice to have

- CAO knowledge
- ISO 13485, 14971, 62366 experience
- IVD field interest

Personal Characteristics

- · Proactive and solution driven
- Team player
- Rigor, autonomy and versatility
- Self-motivated