Regulatory Affairs Head Manager
Permanent position/CDI

Company description:

Electroducer is a startup founded in 2017 by the interventional cardiologist Benjamin Faurie, focusing on designing, developing, and commercializing a IIa disruptive medical device integrating the minimalist approach to simplify and secure percutaneous valves implantations (aortic, mitral, tricuspid) and complex coronary interventions.
Guided by the challenging economic and regulatory context and by the founder's vision focused on the patient, Electroducer is supported by partnerships with internationally renowned experts, hospitals and industrial partners.

In this context, we are looking for a motivated, passionate and experienced person, whiling to work in a small team where the closeness between the Management and co-workers encourages individual autonomy and the power to work together, to fill a permanent position as an experienced **Regulatory Affairs Head Manager.**

The company is based in Grenoble, a French Alps dynamic pole in the Medtech industry.

Purpose of the position:

Supervised by the CEO and working in a small team, your missions consist in:

- Ensuring that regulatory strategies and regulatory activities are effectively executed to meet the business objectives and legal requirements,
- Supporting QMS compliance with regulatory requirements.

Role and responsibilities:

You missions will be divided into two areas of activities:

Regulatory affairs:

- support for activities related to the proper consideration of standards and regulations in the context of the development, manufacturing and marketing of medical devices
- represent the regulatory affairs function for the purposes of implementing the quality management system (risk management, CAPA, change control, etc.)
- responsible for managing the technical documentation of the product for CE marking or non-CE approvals, ensure product Technical Files are maintained and updated
- manage the FDA application
- support to the clinical affairs department for the constitution of clinical investigation request submission files
- interact with project teams to provide regulatory guidance with respect to product development and change control processes
- definition of specifications from regulatory and normative requirements for design and development, participate to the risk management process
- management of product labeling requirements
- maintain current knowledge of relevant regulations and standards, carry out regulatory and standards monitoring as well as materiovigilance monitoring, and formalize the gap analysis between the versions of standards and regulations

- in relation to various services (marketing, communication), ensure the adequacy of the documentation with the applicable regulatory requirements and provide regulatory support in specific projects:
  - participate in post market activities
  - participate in the monitoring actions of products
  - participate in the reporting of incidents to the competent authorities

Quality:

- participation in the development and implementation of the QMS
- management of non-conformities, CAPA, derogations on your area of intervention
- review and approval of documents from the design and development team
- manage internal/external and regulatory audits

Responsibilities:

- Materiovigilance responsible
- Person responsible for Regulatory Compliance (PRRC)

Required skills:

Education:
Bac + 5 or more in regulatory affairs and quality

Experience:
10 years of experience in regulatory affairs / quality in medical devices industries.

Technical Skills:
Good written and oral skills in English
Knowledge of Quality and Regulatory requirements applied to Medical Devices Industries
Good knowledge of CE marking and FDA submissions
Experience of CE audits, FDA inspections

Others (Behavior skills, managerial skills …):
A passion for patient care
Strong interpersonal skills including communication, collaboration / team player
Ability to work autonomously
Customer and consumer focus
Ability to network at multiple levels within and outside the organization
Drive for results
Priority setting
Listening
Ability to federate

Application :

To apply : luiza.morin@electroducer.io with the **job reference QARA-CDI.**
To know more about the company, please visit our website www.electroducer.io