JOB DESCRIPTION

REGULATORY AFFAIRS & QUALITY LEAD

April 2021

REGULATORY AFFAIRS & QUALITY LEAD key responsibilities include:

- Define regulatory strategies for medical devices and combination products in EU and US for product submissions, identifying needs for bench, animal and clinical testing.
- Ensure general RA/QA operational activities (e.g. regulatory watch, PMS, change control, NC/CAPA management etc..)
- Participate on Product Development teams by providing regulatory strategy, timelines, and direction.
- Comply with applicable EU and FDA regulatory laws/standards
- Ensure continuous improvement of the organization through the maintenance of QMS efficiency. Ensure maintenance of ISO 13485 certification.

INTRODUCTION :

DIANOSIC, is a Medtech start-up founded in July 2017. DIANOSIC develops innovative solutions in the field of ENT (Ear, Nose & Throat) to address significant unmet clinical needs. More specifically, DIANOSIC targets chronic rhinitis, chronic sinusitis and intranasal bleeding (epistaxis), which are very common conditions that dramatically impair patients quality of life and have a major budget impact for the healthcare system and the society as a whole (sinusitis being amongst the top 10 most costly diseases for employers).

As DIANOSIC develops new solutions in order to cost-effectively tackle those affections, the need to coordinate critical and complex R&D activities at various levels (biomaterials, polymers, active coatings, resorbable materials, sensors, etc) emerged.

Therefore, DIANOSIC is actively engaged in seeking and finding the right candidate in order to push those activities forward in a timely fashion.

JOB BRIEF:

The Regulatory Affairs Lead (EU/US) will lead and be responsible for managing internal and external aspects of regulatory affairs for medical devices and combination products, including compliance of the QMS with ISO 13485 standard.
The individual will develop the regulatory strategy for the company solutions by interfacing with DIANOSIC's R&D partners, consultants and team members as well as with regulatory bodies (EU notified body, EMA, FDA, etc).

RESPONSIBILITIES :

Principal Duties and Responsibilities:

- **Regulatory strategy**: Provide input on regulatory requirements and regulatory strategies on product development to ensure timely submission and approval. Determine regulatory filing strategies and submission types.

- **Technical documentation management**: Prepare, assemble and submit regulatory submissions in various countries within US and European regions. Participate to R&D activities and provide appropriate input to ensure completeness and compliance of the technical documentation.

- **QMS management**: Responsible for compliance with ISO 13485, Medical Device Regulation EU 2017/745, Medical Device Directive 93/42/EEC.

- **RA/QA contact :** Act as liaison for Company with regulatory agencies (EMA, Notified Body, FDA). Lead audits by regulatory authorities.

- **RA/QA Lead**: Participate upon needs to Scientific Board and Strategic Board discussions. Closely monitor KPIs in order to maintain regulatory costs in line with DIANOSIC BP forecasts

Perform other duties as assigned. Some travel may be required (up to 25%).

REQUIREMENTS :

- Proven experience as a Regulatory manager in pharmaceutical industry.
- Minimum 5 years of experience in Regulatory Affairs with drug development and/or development of combination products.
- Proven experience in receiving regulatory approval for medical device and or combination products submissions.
- Knowledge of ISO 13485, Medical Device Regulation EU 2017/745, Medical Device Directive 93/42/EEC, horizontal ISO norms (including but not limited to ISO 14971, ISO 62366, MEDDEV 2.7.1 Rev4)

- Strategic thinking, innovative mindset and strong business acumen are essential in this role.
- Excellent communication skills
- Leadership and organizational abilities
- Problem-solving aptitude
- Ability to liaise, negotiate and interact with worldwide regulatory agencies; orchestrate meetings and teleconferences, document interactions
- Honest, flexible, dependable, self-motivated team player with the ability to work autonomously.
- Expertise in Microsoft Office applications is required, specifically Microsoft Word, Excel, PowerPoint
- Fluent in French and English. German is a plus.

PACKAGE :

- Fixed salary (13 months)
- Variable part (bonus) : 10% of fixed salary upon achievement of predefined goals

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