JOB DESCRIPTION

CMC REGULATORY AFFAIRS DIRECTOR

June 1st, 2022

SUMMARY:

The primary role of the CMC RA Director will be to provide leadership and direction for all pharma Regulatory Affairs and Quality activities while contributing to pre-clinical and clinical development, medical affairs, and any other critical subjects for the Company. Specifically, the CMC RA Director will be instrumental to bring forward our strategic drug-device combination platform (Active Resorbable Intranasal Scaffold).

The CMC RA Director will serve as the face of the Company to the Industry Associations and health authorities concerning pharma-related RAQA subjects. In this capacity, the CMC RA Director may also interact with external audiences including healthcare providers, payers, regulators, policy makers, patient groups and investors.

The job will provide the CMC RA Director with an opportunity to become our Qualified Person ("*Pharmacien Responsable*").

The CMC RA Director will report to the Chief Scientific Officer.

INTRODUCTION :

Dianosic was founded in 2017 and develops innovative solutions in the field of ENT (Ear, Nose & Throat), a €50 billion, double digit growth, and still largely underserved market.

Our startup operates right at the frontier between Pharma and Medtech, as we see tremendous opportunities for drug-device combinations in this specialty. The project originates from the ENT Department from the University Hospital of Strasbourg, where unmet clinical needs have been identified.

Our main focus areas are Chronic Rhinitis, Chronic Sinusitis and intranasal bleeding (Epistaxis). Noteworthy, Dianosic has a strong French and German footprint in R&D and manufacturing.

Dianosic's strategic goal is to establish new standards of care in Chronic Rhinitis and Chronic Sinusitis with its drug-eluting Active Resorbable Scaffold (ARIS). This drug-device combination ARIS platform, developed with world renowned resorbable polymers experts, has the potential to establish new treatment paradigms. Moreover, our ARIS platform creates immense opportunities to create other verticals, especially in the field of otology, chronic migraine and facial pain.

Given the increasing importance of our pharmaceutical activities, DIANOSIC is actively engaged in seeking and finding the right candidate in order to push CMC Regulatory activities forward in a timely fashion.

Last, dianosic acknowledges that ESG (Environmental, Social and Governance) topics are of utmost importance and takes all necessary actions to ensure they are properly factored in our strategic roadmap.

ROLES & RESPONSIBILITIES

General:

Partner with other members of the company on overall strategic planning. Represent the company and its programs to external audiences.

Develop robust CMC Regulatory strategies and oversee planning and execution for both applications (chronic rhinitis and chronic sinusitis) of the Active Resorbable Intranasal Scaffold (ARIS) technological platform.

Provide subject matter expertise in relevant areas including the mastery of Regulatory changes through new guidelines or position statements from decision makers.

Present regular updates to the members of the company and relevant strategic boards.

Lead the CMC aspect of Drugs and drug device combination Research and Development (R&D) up to marketing approval in EU and USA; Support the Design and Development (D&D) of medical devices as and when needed.

Manage the Industrial manufacturing, distribution, and surveillance of marketed Drugs.

Coordinate the CMC section of Quality Management System.

Plan, execute and manages CDMOs and CMOs audits, selection, and qualification

Propose and manage budgets and resources required for: the clinical development, medical affairs. Participate to budget discussions and preparation for Regulatory Affairs activities.

Ensure effective policies and procedures are in place for respective areas of responsibility and compliance

Acts as Qualified Person (Responsible Pharmacist)

In R&D:

Work in close collaboration with Research & Development, Medical Devices, Regulatory Affairs, non-clinical and clinical internal / external experts.

Lead the CMC development strategy

- Manage CDMOs (selection, qualification, monitoring)
- Coordinate the authoring of IMPD, CMC section of INDs, PSF
- Coordinate the support of appropriate consultants
- Manage technical release of IMP batches
- Participate in CMC R&D strategy
- Manage CMC R&D budgets

Marketed products (drugs, drugs associated with dispensing devices)

- Manage CMOs
- Manage Regulatory variations
- Review executed batch records, CAPAs, OOS, Change controls
- Prepare and lead periodic product revies
- Manage batch recalls
- Coordinate marketed products Pharmacovigilance

- Coordinate regulatory authorities' pharmaceutical inspections
- Manage promotion system
- Manage distribution

Perform other duties as assigned.

SPECIFIC REQUIREMENTS

High level education in pharmaceutical sciences (Master, Engineer, PharmD, PHD…)
10 years' experience in the pharmaceutical industry (negotiable).

Team player
Autonomy
Assertiveness
Basic computer sciences
Professional English
Ability to travel

PACKAGE & KEY JOB FEATURES

Salary to be discussed based on individuals' profiles
Health insurance
Training & development opportunities
Exposure to strategic topics (internally & externally)

Location: flexible

Working conditions: flexible (office, remote or hybrid)