LATTICE MEDICAL IS LOOKING FOR A "QUALITY AND REGULATORY AFFAIRS MANAGER"

Context:

LATTICE MEDICAL is a medtech start-up created by four researchers and entrepreneurs with the idea to lead a revolution in breast reconstruction after a cancer. Thanks to a disruptive technology at the crossroads of innovative materials, 3D printing and regenerative medicine ; mastectomia will be a bad souvenir. Women will get back their former body, without long term implant, without silicon and without long and complicated surgery.

We develop an implantable device allowing regeneration of autologous adipose tissue, a 3D printed implant with fully biodegradable material.

To get the market access in 2024-2025 we are hiring talented people, with a soul of entrepreneur and who want to be involved in human project with international perspective and multidisciplinary team.

Why do we need you?

Breast cancer is a major public health concern that affects one in eight women. To meet the objectives of Health, our business philosophy is that we believe in innovative medicine by adapting the product to the patient. To achieve our purpose, we round with scientific experts and seniors consulting who advice and accompany. You can rely on this network and more formations put on the company.

In order to register our medical device initially in Europe, the USA and internationally, we need a leader who can manage all the regulatory elements, obtain and maintain the CE/FDA mark, establish the link with the regulatory authorities, notified body as well as the experienced Q / AR consultants. Manage the regulatory/quality team, support the implementation of ISO 13485 certification and drive the clinical evaluation plan for our first-in-human in 2022.

Duties & Responsibilities:

- Manage the obtention of CE Mark for our products in development
- Manage the regulatory, clinic and quality team
- Define and manage the global regulatory strategy of our products in development especially for EU and US regulatory system
- Manage the clinical evaluation plan in collaboration with senior consultants in order to enter into clinical phase in 2022
- Follow pre-market clinical investigations with our scientific consultants and physicians
- Manage and develop relationships with notified body, health agencies (ANSM, FDA…)
- Cooperate with R&D department throughout the product development and technical file to ensure compliance with the chosen regulatory strategy.
- Assist the quality manager in the ISO 13485:2016 certification and maintain

- Compile and support the preparation of regulatory submissions including but not limited to EU Technical Documentation, FDA Pre-submission documents, IDE applications, pre-market notifications/applications and post-market reporting.
- Conduct regulatory intelligence/research to maintain current knowledge base of existing and emerging regulations, standards, or guidance documents and recommend changes to company procedures in response to changes in regulations or standards.
- Provide regulatory insight, interpretation and advice to R&D teams internally on new/updated regulatory requirements.
- Participate in internal or external audits and internal training to the team

Qualifications & Skills

- Degree qualified in regulatory affairs, scientific, engineering or a technical discipline.
- At least, five (5) years of regulatory affairs experience in the medical device field especially in class III medical devices
- Understanding of EU Medical Device Regulation and relevant guidelines.
- Understanding of ISO Standards (13485) (FDA CFR Title 21 desiderable).
- To provide a reading grid of the issues related to his/her scope of responsibilities.
- Excellent communication skills (written and verbal) in English and at least one other European Language preferably French;
- Establish responsible communication between internal and external players, while being diplomatic

Job Competencies & Personal Attributes:

- Strong leadership
- Self-starter, energetic, motivated;
- Positive attitude;
- Result and quality oriented approach;
- Ability to multitask & Analytical thinking;
- Self-determination;
- Highly committed personality and a desire to achieve.

Permanent position based in Lille area.

Contact: recrutement@lattice-medical.com