KiOmed Pharma recruits:

"Regulatory Affairs (RA) Manager"

permanent contract /Herstal (Belgium).

Capitalizing on a history of innovation and expertise in exclusive natural chitosan chemistry, KiOmed Pharma, a spinout from KitoZyme, develops a unique pipeline of medical devices that address unmet medical needs in high impact pathologies and major social burdens such as invalidating Osteoarthritis, skin aging and ophthalmology.

Located in Belgium, Herstal and composed of a fast-growing team, KiOmed Pharma has recently launched on the market its first class III CE marked medical device, KiOmedineVSOne® indicated in the treatment of symptomatic patients suffering from knee osteoarthritis. A R&D pre-market pipeline of medical devices is currently under development, more specifically in dermo-aesthetic and ophthalmic diseases.

KiOmed Pharma has the ambition and the resources to grow to a worldwide class and aim at succeeding the commercial launches and growth on its markets.

KiOmed Pharma is looking for an experienced and seasoned Regulatory Affairs Manager to work in close collaboration with the Chief Medical and Compliance Officer.

Missions:

- Pre-market Missions
    - You contribute actively as the regulatory expert, subject matter expert, on proposing the regulatory strategy in the framework of our R&D pre-market programs, to ensure conformity to regulations in force such as MDR for EU markets.
    - You support the R&D team in planning and executing the necessary regulatory activities to progress our Project portfolio with the aim of obtaining CE certification and you directly manage the marketing authorizations outside Europe.

- Post-market Missions
    - You are responsible for the submission and the follow up of the technical dossiers in Europe according to MDR and the marketing authorization applications outside Europe according to local regulations.
    - You contribute to the implementation of changes impacting CE-marked/registered products, ensuring the consistency, maintenance and follow-up of the change management system and the corresponding action plans.
    - You act as the regulatory expert, subject matter expert, on demand, within the company on post-market clinical & non-clinical initiatives when required by other departments, with the review of the documents from a regulatory point of view. You actively contribute, to the maintenance of the QMS in close collaboration with the Quality Officer.

- In link with the other departments, you collect, analyze, and summarize the data from the post-market surveillance (PMS) to communicate them to the notified body.
- You collect, analyze, and process the feedbacks from the market concerning the marketed products requiring the recording of non-conformities or vigilance activities and some CAPA plans.
- You are in charge of entering the required data in Eudamed.
- You check the application of any anti-gift act and sunshine act, depending on the regulation of the countries.

- You actively participate to the regulatory and normative watch and the implementation of the actions to comply with regulation and standards.

- You are in charge of the verification of the promotional documents, training supports for customers, labeling/IFU/SSCP.

Profile:

- Master or PhD in science in pharmacy and in regulatory affairs.
- Excellent knowledge of the Regulation 2017/745 (MDR) and of ISO13485.
- Knowledge of GMP system(s) would be a plus.
- Experience in RA and vigilance of minimum 5 years, preferably in medical devices class III.
- Very good capacity of documents drafting.
- Motivation to work in team in a dynamic environment.
- Rigor, critical mind, analysis capacity and autonomy.
- Strict respect of procedures, quality standards and regulations applicable to the company.
- Excellent level of English (writing/speaking).

Offer:

- An opportunity to participate to the growth of a young and dynamic company in an innovative and fast-moving field, and particularly to the start of its commercial activity in the context of a new European regulation on medical devices.
- A possibility of hiring with a permanent contract.

If you are interested by this proposition, please send your CV and motivation letter in English to the following address:
agnes.cantoro@kiomedpharma.com