**KiOmed Pharma recruits :**

**"Regulatory Affairs Manager"**

**Innovative Medical Devices based on KiOmedine®,**
**an exclusive highly pure non-animal polymer**

Possibilité d'embauche CDI / Herstal (Belgium).

Capitalizing on a history of innovation and expertise in exclusive 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, aesthetic medicine and ophthalmology.

Located in Belgium, Liège and composed of a fast-growing team, KiOmed Pharma has launched on the market its first class III CE marked medical device, KioMedine$^{VS}$one® 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 medicine and ophthalmologic 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.

**Objectives / Purpose:**

The Regulatory Affairs Manager is responsible for leading the regulatory strategy from preparation of registration dossier to post-market follow-up in order to achieve development and marketing goals for medical devices. He/She leads, in collaboration with other departments, the activities related to market authorization, registration and vigilance. The Regulatory Affairs Manager is under the supervision of the Chief Operating Officer.

**Responsibilities:**

- Support and provide guidance on regulatory issues to internal and external persons on assigned projects.
- Execute or support the preparation and maintenance of new and existing documents required for regulatory approval for assigned projects.
- Gain and maintain regulatory authority approval and manage follow up post-approval activities, including vigilance-related activities, for assigned projects.
- Liaise with regulatory authorities, including notified bodies, as required.
- Participate to product change control activities.
- Monitor legal and regulatory related issues for medical devices, as well as progression in standardization work.

- Report to the upper management on any regulatory update or issue impacting the company activities.
- Ensure documents are produced in accordance with applicable internal and external procedures, guidelines, regulations and standards

**Profile:**

- University degree (Master or Ph.D) with a scientific (preferably medical or pharmaceutical) or regulatory affairs orientation.

- 5-years' experience in regulatory affairs.
- Possessing a strong knowledge, understanding and experience concerning European regulations and quality systems for medical devices (MDR 2017/745 et ISO 13485). Knowledge and relevant experience in other territories (US, China, Brazil) or regulation for medicines (Directive 2001/83, GMP) will be regarded as an additional advantage.
- Strong communication and organizational skills. In addition, you are accurate, self-disciplined, proficient in multitasking and a real team player.
- Ability to analyze and summarize scientific and technical information.
- Ability to work across function and in a changing environment.
- Strong oral and written communication skills in English and French. A proficiency in other languages will be regarded as an advantage.

**Offer:**

A position within an innovative biotech company having a proprietary and unique technology targeting unmet medical needs in multibillions markets.
An attractive package in line with the responsibilities and your experience.

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