KiOmed Pharma recruits:

"Regulatory Affairs (RA) Officer"

Innovative medical devices for regenerative medicine.
Possibility of hiring with permanent contract / Herstal (Belgium).

Located in Belgium and composed of a fast-growing team, KiOmed Pharma is a high-potential biotech company specialized in the research and development, manufacturing and commercializing of innovative medical devices for regenerative medicine.

KiOmed Pharma has currently two products targeting orthopaedic and tissues regeneration markets that will get CE-marked early 2020, and other innovative developments in the pipeline.
KiOmed Pharma has the ambition and the resources to grow to a worldwide class and aim at succeeding the commercial launch and growth on its markets.

KiOmed Pharma is looking for a RA Officer to work in close collaboration with the Chief Compliance Officer.

Missions:

- You actively participate to the preparation and submission of the technical dossiers in Europe and outside Europe, as well as to the maintain of the existing technical dossiers.
- You actively contribute to the action plan of the Quality Management System transition through to the European regulation concerning medical devices (MDR).
- You collect, analyze and summarize the data from the post-market surveillance (PMS) in order 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 contribute to the implementation of changes impacting CE-marked products, ensuring the consistency, maintenance and follow-up of the change management system and the corresponding action plans.
- You actively participate to the regulatory and normative watch.

Profil:

- Master or PhD in science or in pharmacy.
- Work experience in ISO 13485 and/or GMP system(s) and good knowledge of regulatory requirements concerning the medical devices (MDD and MDR).
- Experience in RA, PMS and/or vigilance of 3-5 years.
- 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.
- Good 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

Applications accepted until February, 28th 2020 included.