Regulatory Affairs Coordinator

DIAsource ImmunoAssays® SA is a Belgian company active in the in-vitro diagnostics sector. Our medium-sized company (80 employees) is based south of Brussels (Louvain-la-Neuve in Belgium) close to the University of Louvain-la-Neuve (UCL). We are specialists in immunoassay development, manufacturing and distribution since more than 30 years, with a specialization in Vitamin D. We serve customers in over 70 countries, both direct as through our network of distributors and OEM partners.

In the light of the growth and development of our company, we are recruiting a **Regulatory Affairs (RA) Coordinator** for our offices in Louvain-la-Neuve.

The **Regulatory Affairs (RA) Coordinator** ensures the appropriate licensing, marketing and legal compliance of our medical products in order to control the safety and efficacy of it. He/She combines his/her knowledge of scientific, legal and business issues to ensure products, which are developed, manufactured and distributed by a wide range of companies, meet the required legislation.
The Regulatory Affairs Coordinator is the crucial link between the company, its products and regulatory authorities in the different main territories such as Europe (CE) and the US (FDA).

Tasks

- Ensuring that DIAsource's products comply with the regulations;
- Keeping abreast of international legislation, guidelines and customer practices in all countries that the company is exporting to;
- Collecting, collating and evaluating scientific data that has been researched by colleagues;
- Developing and writing clear arguments and explanations for new product licenses and license renewals;
- Maintaining professional relationships with the regulatory authorities for the registration of new products;
- Coordinating and implementing the product registration plan, incl. coordination of the prioritization of registration pipeline needs and proposals;
- Preparing submissions of license variations and renewals to strict deadlines;
- Monitoring and setting timelines for license variations and renewal approvals;

- Advising scientists and manufacturers on regulatory requirements;
- Continuously updating of relevant regulatory guidelines and knowledge.

Qualifications and skills

- Process oriented
- Critical, analytical and structured mind: rigorous, structured, orderly, attention to detail
- Self-organized, autonomous, self-driven
- Good written and verbal communication skills
- Team player
- Diplomacy
- Efficient in use of IT systems
- Excellent to good mastery of spoken and written English is a key requirement, French is needed as operational language. Dutch is an asset.

Desired Education and Experience

- Bachelor or Master degree in scientific discipline;
- Experience not strictly required, but knowledge in clinical research and/or regulatory is an obvious plus.

How to apply?

Please send your CV together with a letter to hr@diasource.be Ref. RA Coordinator. Your application and related information will be treated with strict confidentiality.