



Regulatory Affairs Specialist

Brussels Area, Belgium

Come and join a leading global manufacturer as a Regulatory Affairs Specialist, in this exciting and career developing role. Great opportunity to work within the global regulatory environment, inclusive of APAC, LATAM and the Middle East. A unique opportunity to further develop your expertise within this global role.

The Company

This global company develops exciting and innovative products in the area of medical devices and IVD, providing you with fantastic access to a broad product portfolio. Not only allowing you to develop your skills further but also ensuring two days are never the same! This company's products are globally recognised and are producing groundbreaking products to handle the COVID-19 pandemic.

This is a fantastic opportunity to work in a company where you will be regarded as more than just a number. With exposure to international environments and a vast portfolio, you can ensure your personal and professional development are the forefront of the company's mind. The portfolio of products will cover both IVD and medical devices, inclusive of Class III products. Further to this, you will be registering the products globally; inclusive of the EMEA region.

We are looking for a Regulatory Affairs professional to join this team and build on their experience already gained in medical technology. If you are the kind of person who sees beauty in complexity, challenges instead of obstacles and enjoys being hands-on this is the perfect position for you!





The Role

As Regulatory Affairs Specialist your responsibilities will include but not be limited to:

- Oversee a vast product portfolio, including both medical devices and IVD.
- Working on global projects, covering APAC, LATAM and EMEA.
- Collaborate in cross-functional teams on new product development projects; marketing, R&D, quality, regulatory, technical to support the international registration process.
- Working directly with the Ministry of health to ensure successful product registration.
- Support the transition from MDD to MDR and IVDD to IVDR.
- Handles regulatory documentation requests from other departments.

Role Requirements

The ideal candidate for this role will have:

- Bachelor's degree in science/engineering or equivalent qualification.
- 1+ years experience within Regulatory Affairs in a medical device or IVD context.
- Expertise within the international registration process.
- Experience within CE marking would be a bonus for this role.
- Any experience of working on projects with MDR and IVDR are considered a plus.
- Fluent English is required for this role. Fluency in French is a bonus.

Find out more about this exciting and fast moving opportunity! Be part of a global team and develop your expertise across an exciting product portfolio.

We'd love to hear from you!

Please send your CV to clarisse@elemed.eu for a confidential career discussion.

