Regulatory Affairs Specialist

Occlutech is the leader in developing innovative products for the treatment of structural heart disease. The Company manufactures, develops, sells and markets Class III medical devices for the transcatheter repair of structural heart defects, including a range of specialized devices for patients with atrial fibrillation or heart failure, in over 90 markets around the world. Occlutech operates facilities in Germany, Turkey and Sweden.

Location: **Helsingborg, Sweden**

As Regulatory Affairs Specialist you will be a key team member of the Regulatory team based in Helsingborg, with further colleges in Germany and Turkey. Your everyday work will be in close collaboration with supply chain, customer service and product management as Helsingborg is the distribution center of Occlutech.

Your work will focus on

- Submission, surveillance and maintenance of international product registration including the preparation, legalization and shipment of regulatory documents
- Submit documents and timely responses with international regulatory bodies, in accordance with local and international regulation
- Routine maintenance of approved files, including coordination and preparation of amendments as necessary
- Communication with suppliers, distributors or sales representatives
- Support the senior RA manager in the development of relevant regulatory procedures and work instructions
- Provide regulatory oversight of changes in manufacturing facilities, processes, and procedures, as these changes pertain to international regulations
- Coordination of, review, and submission of requests for Compassionate use of medical devices
- Reports on status, changes or any news to management
- Co-ordination of additional test procedures and shipment of testing material
- Is flexible and open to provide assistance in non-specific daily work tasks when and wherever needed

We are looking for a candidate, who

- Has a BS degree in engineering or life sciences
- Has a minimum of 2 years of experience in the medical device, IVD or pharmaceutical industry
- Has a minimum of 1 year of experience in regulatory tasks in medical device industry
- Has experience with cardiological devices is a plus
- Ideally have knowledge of requirements in accordance with MDD 93/42/EEC, relevant regulations, international standards (ISO 13485) and guidance documents (MEDDEVs, etc.)
- Can maintain confidentiality in dealing with regulatory documentation
- Can prioritize and handle several projects concurrently, and to meet strict deadlines

Are you interested?

For more information contact us at HR@Occlutech.com

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