Director of Regulatory Affairs m/w/d

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 85 markets around the world. Occlutech operates facilities in Germany, Turkey and Sweden. For additional information please visit our website at www.occlutech.com.

Location: **remote**

The Director of Regulatory Affairs is responsible for leading the US Regulatory organization. This position will set the overall strategic direction for Regulatory Affairs and work collaboratively across multiple functions and external governing bodies to ensure Occlutech products meet the needs of our patients, customers, and remain compliant to US regulations.

Essential Duties and Responsibilities:

- Provides strategic direction and operational leadership for regulatory affairs in the US
- Develops and communicates effective regulatory strategies, to meet established business goals.
- Authors 510(k)s, IDEs, PMAs, and other FDA regulatory submissions.
- Leads all US Regulatory Affairs functions at Occlutech and ensures corporate goals of introducing new products and supporting existing products in the marketplace are met.
- Acts as primary interface with applicable regulatory bodies, presenting strategies and technology communications effectively.
- Premarket: Negotiate with regulatory authorities during the review process to ensure submission approval and preapproval compliance activities are completed
- Post Market: Oversee regulatory aspects to ensure compliance. Required periodic FDA submissions post PMA Approval. Review and approve promotional items to ensure regulatory compliance. Represent Regulatory affairs in the event of a product recall.
- Establish US regulatory strategies, including long term Company vision and ensure alignments with all functions in the organization. Ensure the development and execution of regulatory strategies and plans to enable efficient development of products in the portfolio.

- Ensures that all regulatory activities are conducted with the highest integrity in an ethical, legal and compliant manner.
- Develops the infrastructure (employee/contracted) and capability to maintain compliance with all regulatory requirements applicable to the company's programs, business activities and products.
- Represents the Company and serves as the official correspondent to FDA.
- Designs and implements regulatory strategies and oversight in support of submissions, device labeling and promotional materials for US products.
- Maintains external visibility to new and changing regulatory trends and guidance as input to the overall Occlutech strategies.
- Identifies areas of regulatory or compliance risks and develops mitigating strategies.
- Works collaboratively with key internal stakeholders such as Research & Development, Clinical, Operations and Marketing.
- Collaborates with European Regulatory team.

Knowledge, Skills and Abilities Required for a Successful Job Performance:

- Bachelor's degree required
- At least 5-7 years of Regulatory leadership experience within medical device in the US
- IDE and PMA experience required
- Proven track record of establishing effective relationships with regulatory agencies, including the FDA
- Experience securing approvals for medical devices
- Experience acting in the capacity of Management Representative with FDA and external governing bodies
- Excellent communications skills across all levels of the organization with the ability to influence through constructive and collaborative means

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Occlutech

Desired Knowledge, Skills and Abilities:

- A consummate team player with a flexible and creative approach
- Proven track record of success
- Experience and familiarity with medical devices used in the treatment of Structural heart disease and other cardiovascular diseases

Are you interested?

We look forward to receiving your application (cover letter, CV, including qualifications and references - all documents in one pdf file), your salary expectation and the earliest possible date for start of work to bewerbung@occlutech.com . Only applications in English will be evaluated.

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