Regulatory Affairs Specialist 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: **Chicago area or remote**

Reporting to the Dir of Regulatory Affairs, the RA Specialist is responsible for assisting in the support and execution of the regulatory and compliance strategy for Occlutech. The RA Specialist will support day to day regulatory operations including providing regulatory advice and support to assigned project teams, assessing lifecycle changes (design control), preparing regulatory submissions, and reviewing critical documents to determine applicability and acceptability for regulatory submission.

In addition, the RA Specialist will assist the organization in ensuring regulatory compliance to established standards/guidance and implementing procedures to ensure that the business unit's regulatory program is effective and efficient. The RA Specialist will look ahead at the changing regulations and proactively ensure the organization's compliance to established standards and regulations. The RA Specialist will provide guidance and work jointly with the project teams and key stakeholders to ensure compliance and regulatory goals are met while also achieving excellence.

This position will work closely with other functional areas, such as Quality, Engineering, Operations, and Marketing to assure alignment to commercial regulatory requirements of company products.

Essential Duties and Responsibilities:

- Prepares regulatory submissions (IDE/PMA/HDE supplements, amendments, annual reports, etc.) for new product presentations and/or lifecycle changes.
- Represents and provides regulatory guidance within the cross-functional/project team and presents agreed upon regulatory positions.
- Assesses the status of lifecycle changes to product, product labeling, processes, materials, etc. that is subject to an active application. Works independently with other functional areas to obtain all information required for change requests and submissions. Determines regulatory requirements and notification for such changes.
- Interprets regulations and implements Regulatory Affairs policies and SOP's to ensure organization's regulatory compliance.

- Identifies and communicates regulatory needs and strategies.
- Supports UDI and GUDID Database operations.
- Reviews critical documents and determines applicability and acceptability for regulatory submission, seeking guidance when necessary.
- Understands the content of the submission information and ensures consistency within dossiers. Able to follow scientific arguments and ensure data is complete and sound.
- Exercises good judgment within policy and regulations.
- Must be able to easily deal with complexity, uncertainty, and large bodies of work.
- Interface with other team leaders to ensure coordination and implementation of consistent standards and processes.
- Assess proposed regulations and communicate new requirements and their probable effects.
- Other duties as assigned by Regulatory Affairs leadership.

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

- 3 years of experience in Class III medical device industry or equivalent, with a minimum of 2 years in Regulatory Affairs.
- Bachelor's degree in biology, chemistry, engineering, or a related subject is required.
- Must be able to interpret and apply government regulations.
- Must be experienced in the translation of regulatory requirements into practical plans.
- Must be a proactive contributor and problem solver, and work in close collaboration with others.
- Strong organizational and planning skills, as well as strong attention to detail.
- Accountable for results and goal attainment.
- Ability to work independently with limited supervision, adapt to change and manage multiple tasks.
- Technical knowledge of Class III Medical Device regulations.

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- Strong computer skills in Word, Access and Adobe Acrobat and working knowledge of electronic publishing/file management.

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 at Occlutech. Only applications in English will be evaluated.

bewerbung@occlutech.com
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