Clinical Program Manager

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. For additional information please visit our website at www.occlutech.com.

Location: **Chicago Area or remote**

The Clinical Program Manager will provide global leadership in the management, oversight, planning, coordination, and execution of ongoing and new clinical activities, providing input to clinical development strategies in alignment with business objectives. Responsible for the oversight of Clinical Affairs staff, project management activities including the successful execution of clinical milestones in compliance with applicable clinical/regulatory standards, facilitation of effective internal and external relationships, and achievement of Clinical Affairs department goals. In addition, this role will be responsible for publication management for Occlutech products.

Your work will focus on

- Managing applicable staff and program(s) / project(s) and ensure appropriate resources are maintained for assigned projects.
- Providing direction, subject matter expertise, training materials, and mentoring to the Clinical Research team to support corporate and departmental objectives and the building of high performing teams.
- Responsibility for managing the design, development, modification, and evaluation of all clinical execution plans (eg protocol, data forms, consent forms, source document worksheets, budget, timelines, gap analysis, etc)
- Accountability for the comprehensive clinical trial activities including but not limited to study start-up, site activation, site management, vendor oversight, study reports, site and study close-out.
- Providing technical direction in contract research organization (CRO) and vendor selection/management as needed to execute clinical trials.
- Working closely with hospitals and investigators participating in the clinical trial and maintaining close working relationship with KOLs, other investigating physicians and site coordinators
- Providing input and support for post-clinical activities and market launch of products.

- Establishing / supporting cross-functional Core Teams to ensure optimal alignment of Clinical, Regulatory, commercial goals, site operations, data monitoring and review, and safety surveillance and reporting expectations.

- Ensuring clinical research programs are conducted in accordance with company standard operating procedures (SOPs), Good Clinical Practice (GCP), and regulations, as applicable.

- Work with Regulatory authorities such as FDA on study design, study endpoint, and reporting of results.

- Publication management.

We are looking for a candidate, who

- Has an university degree (minimum Bachelor of Science) with 5-7 years of global clinical development and/or clinical research experience including medical device experience, or the equivaltent training and experience.

- Has comprehensive knowledge of clinical operations including all applicable US regulations for Medical Devices (eg Class III) and GCP, managing CROs and consultants. Working knowledge of OUS regulatory requirements (eg EU, LATAM, AsiaPac).

- Must be knowledgeable of Cardiology therapeutic devices and procedures, experienced in structural heart disease treatment, and have had broad exposure to clinical trials of either devices (preferred)

- Has experience with site and sponsr level FDA BIMO investigation(s)

- Working knowledge of data management, safety surveillance and reporting, and Health Economic and Reimbursement strategies.

- Has superior problem-solving skills

- Has excellent interpersonal and effective verbal and written communication skills and be able to effectively work across departments with diverse needs

- Has excellent organizational and time management skills

- Has ability to adapt to changing priorities

- Has proficiency in MS Office applications

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Occlutech

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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