Clinical Research Associate

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 preferred, remote work considered**

The Clinical Research Associate ensures clinical research studies are conducted in accordance with the protocol, standard operating procedures, good clinical practice, and applicable regulatory requirements by managing assigned sites.

Your work will focus on

- Site selection, start-up/regulatory, initiation, monitoring and close out visits using good clinical practices, applicable regulations, SOPs and work instructions.
- Providing protocol, GCP, and related study training to assigned sites.
- Establishment of regular lines of communication with sites to manage ongoing study expectations and potential issues.
- Evaluation of quality and integrity of study site practices related to the proper conduct of the study and adherence to applicable regulations. Escalation of quality issues to Clinical Project Manager.
- Executing assigned work efficiently and adhere to project timelines.
- Managing the progress of assigned study sites by documenting regulatory submissions and approvals, recruitment and enrollment, Case Report Form (CRF) completion and submission, and data query generation and resolution.
- Creation and maintenance of appropriate documentation regarding site management, monitoring visit findings and action plans by submitting regular visit reports, generating follow-up letters, essential document collection and filing and other required study documentation.
- Travelling for in-house CRA in office environment: about 30%; for Field CRA about 60% and occasional weekend travel.

We are looking for a candidate, who

- Has a Bachelor's Degree in a scientific field and 3 years of monitoring experience; or equivalent combination of education, training, and experience.
- Has IDE-PMA and/or IDE-510k monitoring experience.
- Has ACRP or SoCRA certification.
- Has good knowledge of applicable clinical research regulatory requirements, i.e., Good Clinical Practice (GCP), International Conference on Harmonization (ICH) guidelines, and ISO 14155.
- Has proficiency in Microsoft Office Applications.
- Has strong written and verbal communication skills
- Has good organizational, interpersonal and problem-solving skills.
- Has strong attention to detail.
- Has time management skills.
- Has ability to establish and maintain effective working relationships with coworkers, managers and clients and site personnel at assigned sites.

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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