Clinical Trial Assistant (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 or remote**

The Clinical Trial Assistant provides operational support to Clinical Affairs staff.

Essential Duties and Responsibilities:

- Assist in compiling data from study specific systems (e.g., eTMF, CTMS, EDC) to support on-going site visit / monitoring activities.
- Assist clinical project team in Electronic Data Capture (EDC) development and User Acceptance Testing (UAT)
- Responsible to support device accountability and other study supply shipping and tracking
- Assists with collection and organization of required records of study activity, including Case Report Forms (CRFs), study records and/or regulatory forms.
- Responsible to maintain study-specific electronic trial master file (eTMF) and escalate any issues.
- Accountable to support study meetings by drafting and distributing agendas and minutes.
- Responsible for assisting with Investigator Meeting organization tasks (e.g., printing and distributing handouts, collecting, and filing attendance sheets, securing reservations, processing payments)
- Interfaces with monitors/vendors/study personnel to address and resolve study-related issues.
- Responsible for study level invoice processing, tracking, and reporting.
- May contribute to site management through remote and/or monitoring support.
- Responsible to assist with coordinating activities to support the development of study documents (e.g., protocol, study plans, clinical study report)
- Accountable to support general filing and record keeping for the Clinical Affairs Department

- Availability to work evenings and weekends intermittently as needed.
- Perform other duties and responsibilities as assigned.

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

- Bachelor's Degree in a scientific field with 3 years' experience in clinical research, or equivalent combination of education, training, and experience.
- Experience in the medical device industry (strongly preferred)
- Experience with MS Office Suite

- Knowledge of applicable clinical research regulatory requirements, i.e., Good Clinical Practice (GCP), International Conference on Harmonization (ICH) guidelines, or ISO 14155
- Strong collaborative skills.
- Excellent written and oral communication skills.
- Extremely detail oriented.
- Good organizational, interpersonal, and problem-solving skills.
- Ability to maintain strict confidentiality.

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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