Clinical Research Associate (f/m/d)

Occlutech is a leading specialist provider of minimally invasive cardiac devices, with a mission to improve the quality of life for people with heart conditions. The vision is to become a global leading specialist provider in cardiac devices, addressing congenital heart defects, stroke prevention and heart failure.
Occlutech has a broad and proven portfolio, based on proprietary technology, and over 200 patents with more than 139,000 products sold. The company markets and sells its products in about 85 countries and has around 300 employees.

The **Clinical Research Associate** ensures the overall quality of clinical trials by monitoring study data and managing site adherence to the protocol, all applicable regulations and related study documents. The CRA is the primary contact with the study site and serves as the liaison between clinical investigators and the Sponsor.

Your work will focus on

- Planning, preparing and managing all monitoring related activities, performance of monitoring of trial / registry sites

- Conducting clinical trials, clinical studies and registries according to all applicable regulations, to commonly accepted practices, and to Occlutech's internal guidelines, i.e.

    - Prepare Essential documents according to ISO 14155, MDR
    - Care for submission-approvals by Competent Authorities and favorable opinions by responsible Ethics Committees
    - Plan and track the course of the studies and update tracking lists
    - Liaise with study investigators and site staff on a regular basis
    - Oversee and lead subcontractors such as, but not limited to, data management, local monitors

- Assisting in Study audits
- Communication between investigators / site staff and Occlutech
- Providing regular updates to CRM on trial status, plans and bottlenecks
- Contributing to the Occlutech QM system

Requirements, Knowledge, Skills and Abilities

- A Bachelor's and/or a Master's degree on science or health related field
- A minimum of 3 years' experience in the field of clinical research
- Knowledge of relevant government regulations, standards and guidelines
- Knowledge on Medical Device Regulation (MDR)
- Strong analytical and problem-solving skills & excellent interpersonal and communication skills & team player.
- Proven track record of working in a dynamic, international environment
- Proficient user of computer applications, software's for the execution of daily project operations
- Experienced in using a Clinical trial management system (CTMS) or equivalent
- Ability to travel when it is needed

- Excellent written and spoken English and German knowledge.
- Excellent written and verbal communication skills are required. Demonstrated proficiency with ICH, and GCP,ISO is required

Working Conditions:

- The CRA position is a remote position requiring about 75% travelling.

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

For further information on Occlutech please refer to:

www.occlutech.com

www.occlutech-jena.de

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