Clinical Research Associate

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 circa 85 countries and has around 320 employees.

Position: Clinical Research Associate (m/f/d)

Location: Istanbul, Turkey

Your work will focus on

*Planning, preparation, and management of all monitoring-related activities, the performance of monitoring at trial/registry sites
*Conduct of clinical trials, clinical studies, and registries according to all applicable regulations, to commonly accepted practices, and to Occlutech's internal guidelines, i.e.

- Preparation of 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

*If required, assist in study audits
*Being the main line of communication between investigators/site staff and Occlutech
*Provide regular updates to Clinical Research Manager on trial status, plans, and bottlenecks
*Contribute to Occlutech QM system (e.g., preparing SOPs)
*Perform other related duties and responsibilities, on occasion, as assigned
*Flexibility and openness to provide assistance in non-specific daily work tasks when and wherever needed

We are looking for a candidate, who has

- Bachelor's and/or a Master's degree in 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

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- Knowledge on Medical Device Regulation (MDR)
- Experience in the use of computer applications and software for the execution of daily project operations
- Experience in the use of a Clinical Trial Management System (CTMS) or equivalent
- Ability to travel when it is needed
- Excellent English and Turkish language skills, written and spoken
- Excellent written and verbal communication skills
- Demonstrated proficiency of ICH, and GCP, ISO 14155 is required

If you are

- Have strong analytical and problem-solving skills, excellent interpersonal and communication skills
- Value and support teamwork
- Have a proven track record of working in a dynamic, international environment
- We offer you an interesting job in a team of people who like to work together and always focus on helping our customers to save and improve patients' lives with innovative and highest quality products

Are you interested?

We look forward to receiving your application (cover letter, CV, references - all documents in one pdf file), your salary expectation and the earliest possible date for start of work to tugce.erdogan@occlutech.com

www.occlutech.com

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