Clinical Research Associate (m/f/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 over 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: Jena or Bonn

The CTA will assist in the conduct of clinical trial activities such as to support in submission process, to ensure appropriate documentation and to prepare relevant trial specific documents and communication with trial sites.

A motivated team will welcome you to meet the challenges of clinical research together. After a detailed introduction period, you will organize your tasks independently and will be offered opportunities for further professional development.

Your work will focus on:

- Plan, prepare and manage all monitoring related activities, performance of monitoring of trial / registry sites
- Conduct 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
- If required, assist in Study audits
- Main line of communication between investigators / site staff and Occlutech
- Provide regular updates to CRM on trial status, plans and bottlenecks
- Contribute to Occlutech QM system

We are looking for a candidate, who has

- 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
- Proven track record of working in a dynamic, international environment
- Experience on using on Clinical trial management system (CTMS) or equivalent
- Excellent written and spoken English and very good German knowledge
- Excellent written and verbal communication skills are required.
- Demonstrated proficiency with ICH, and GCP,ISO is required

If you are

- a team player who likes challenges
- a proficient user of computer applications and standard office software for the execution of daily project operations
- excellent in communication, organization and time management
- open to travelling when needed

Then we can 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 patient's 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 bewerbung@occlutech.com .

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