Clinical Research Associate (m/w/d)

Clinical Research

We are offering a position in the medical device sector with ambitious and passionate people building meaningful products for patients all over the world. Our work environment is agile and allowing for collaboration with smart people and knowledge sharing in cross functional teams. As a fast-growing organization, we provide ample room for development and our remote work policy allows for more flexibility for our employees.

About the position

The Clinical Research Associate 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 young and motivated team will welcome you to meet together the challenges of clinical research. After an introduction period, you will have freedom for self-organization to fulfill your tasks. We also offer 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
- If required, assist in Study audits
- Main line of communication between investigators / site staff and Occlutech
- 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

Our benefits

- A secure job in the medical device industry in a family-friendly working environment
- An interesting work scope in a growing international company
- Comprehensive onboarding and training plan in the first 6 months
- Company wide Mentoring program
- Good work-life balance through 30 days of vacation, flexible working hours and hybrid, family-friendly working time models
- Employer-financed retirement insurance
- Team building, employee and company events
- Easy access to the office on the Beutenberg Campus with an attached canteen
- Healthy work culture with a fruit basket, tea, water and coffee as well as regular team sporting events

- Provide regular updates to CRM 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

We are looking for a candidate, who

- Has a university degree (min. Bachelor) preferably Master's degree in life science or engineering or natural sciences
- Has at least 3 years of professional experience in the field of Clinical Research
- Has knowledge of Medical Device Regulation (MDR)
- Demonstrates proficiency with ICH, and GCP,ISO
- Used to work in a dynamic, international environment
- Has experience on using on Clinical trial management system (CTMS) or equivalent
- Communicates well in German and English
- Is able to work independently, adapt to changing tasks in a fast and dynamic work environment and manage multiple tasks
- Has good organizational, interpersonal and problem-solving skills and is able to collaborate with cross-functional teams
- Is proficient in Microsoft Office applications
- Is able to travel when it is needed

Ready to apply?

We look forward to receiving your application (cover letter and CV to bewerbung@occlutech.com .

Only applications in English will be evaluated.

About Occlutech

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 190,000 products sold. The company markets and sells its products in over 80 countries and has around 330 employees.

Contact

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Occlutech