Clinical Scientific Manager

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 90 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 area**

The Clinical Scientific Manager plays an important role in the planning, managing and evaluating of state-of-the-art clinical projects. He/she performs research work, develops and maintains good relationships to opinion leaders and supports the clinical team in all technical and scientific tasks.

Your work will focus on

- *Managing and writing Clinical Evaluation Reports and Plans, Literature Search Documents, PMCF Plans-Reports and Clinical Safety Management documents of products.*
- *Integrating quality and regulatory changes into clinical documentation.*
- *Evaluate safety reporting of studies with collaboration of Clinical Data Manager and Clinical Project Managers of studies.*
- *Developing and implementing clinical trial plans with CRM and CPM.*
- *Supporting the Clinical team with technical expertise.*
- *Researching, collecting, presenting and offering expert opinion on scientific, medical and regulatory information.*
- *Managing the integrity and accuracy of scientific, medical and regulatory data.*
- *Assisting in audits.*
- *Developing good relationships with opinion leaders*
- *Contributing to the Occlutech QM system*

We are looking for a candidate, who

- *Has an a Medical Degree (MBBS) or PhD.*
- *Has relevant experience to perform requiremtents independently.*
- *Preferably has CMPP Certificate.*
- *Has a minimum of 5 years' experience in the field of clinical research with 2 years in a lead role.*
- *Has knowledge in cardiovascular medicine.*
- *Has profound knowledge of relevant government regulations, standards and guidelines and experience on Medical Device Regulation (MDR) and ISO.*
- *Has proven track record in developing medical education programs.*
- *Has proven track record of working in a dynamic, internatinal environment.*
- *Has strong analytical and problemsolving skills and excellent interpersonal and communicational skills*
- *Is a team player who likes to work in a dynamic international environment*
- *Has experience in using clinical trial management systems*
- *Is open to travel when needed*
- *Has excellent knowledge of English and excellent communication skills. Demonstrated proficiency with ICH, and GCP, ISO is required*

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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