Clinical Compliance Manager (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 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: **Chicago or remote**

The Clinical Compliance Manager is responsible for ensuring clinical research activities conform to federal, international and local regulations and Occlutech procedures and expectations.

Essential Duties and Responsibilities:

- Manage clinical process audits to applicable standards, regulations and company procedures/policies.
- Collaborate with Clinical management to understand needs and establish priorities.
- Conduct internal and external audits (internal systems, trial master file, investigator sites, clinical service providers) to assess the accuracy and quality of scientific data collected, and to determine the level of compliance with applicable regulations.
- Author audit reports that establish the outcome of the audit and detail the non-conformances identified during the audit.
- Track audit results, including corrective actions, and provide follow-up to these actions, as required.
- Analyzes audit findings for trends and provides clinical management with regular reports.
- Identifies regulatory or compliance risks and suggest potential resolutions.
- Perform Supplier Audits, as needed.
- Prepares investigator sites for FDA or other regulatory agency inspections and assists in preparation of written responses to findings.
- Supports the preparation, coordination, and management of regulatory agency inspections. During inspection, plays lead role as facilitator and communicator.
- Provides oversite of Clinical CAPA activity

- Reviews SOPs and WIQs to assure compliance with regulations, update documents or author new documents as needed
- Oversees management of the clinical audit program. Develops clinical audit procedures, processes, and plans.
- Manage the Approved Supplier List for clinical including scheduling for supplier audits
- Communicate effectively and efficiently by both written and oral modes.
- Demonstrate the ability to identify, analyze and report opportunities for improvements and execute solutions.

Knowledge, Skills and Abilities Required for a Successful Job Performance:

- Bachelor's degree in Science. Advanced degree preferred.
- 5-7 years of related work experience in Clinical Compliance / Quality with a strong understanding of audit processes. Experience in medical device preferred.
- Subject Matter Expert of FDA, ISO and other associated regulations pertaining to Clinical Study activity.
- Strong leadership competencies - particularly communication, collaboration, planning, innovation, and strategic thinking.
- Strong attention to detail
- Proficiency with Microsoft Office applications
- Occasional domestic and international travel to clinical sites for meetings and/or audits (up to 25%)

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.

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