TISSIUM

Clinical Affairs Manager

Contract: CDI, permanent

TISSIUM is a fast-paced medical device company, dedicated to the development of innovative tissue reconstruction solutions. We are leveraging our technology platforms to develop novel solutions to disrupt the field of surgery and positively impact the life of patients.

We are actively looking to recruit a **Clinical Affairs Manager** to be part of Tissium's Development Factory. This person will manage and execute the company's clinical strategy, ensure compliance with each country's regulations and guidelines, as well as assess the clinical needs for the company's existing and future products.

Duties & Responsibilities

- ✓ Manages the clinical trials (building of the RFP, selection of CROs, implementation of clinical trial activities from study set up through final version of clinical study report, ensuring that requirements of GCPs and relevant SOPs are met);
- ✓ Actively participates in the writing of clinical and regulatory documents (e.g. study synopsis and study protocols, informed consent form, investigator brochures, clinical study reports, annual reports, design dossier etc.);
- ✓ Manages the study related vendors and serves as the primary contact point for contracted CROs, study staff and contract labs. Identifies potential risk and resolves issues with CROs;
- ✓ Reviews all documents related to the clinical studies in coordination with CROs;
- ✓ Communicates directly with the study staff and the investigators, tracks patient recruitment rates and supports safety monitoring and ethic committee submissions;
- ✓ Performs and/or oversees site monitoring visits for clinical trials as needed;
- ✓ Coordinates the negotiation of site budgets within the set guidelines and provides oversight for site payments and contracts;
- ✓ Ensures availability of study products for the clinical investigation, facilitates site study product orders and ensures site accountability records are maintained;
- ✓ Maintains, in collaboration with CRO staff, clinical trial master files to ensure compliance with required regulatory and GCP standards and consistency with the company's SOPs;
- ✓ Manages the Trial Master File (set-up and follow-up);
- ✓ Provides input and support to maintain appropriate documentation for safety monitoring and submissions to regulatory authorities;
- ✓ Participates with CROs and provides support to sites to prepare for clinical audits and to respond to audit findings conducted by QA and/or external regulatory agencies;
- ✓ Participates in investigators' meetings in order to ensure proper training (study protocol, GCP…) to all persons involved in the clinical investigation;

Qualifications & Skills

- ✓ Master's or PhD degree in life sciences;
- ✓ Excellent spoken and written English;
- ✓ Minimum of 3 to 5 years of clinical study management experience in the medical device industry;
- ✓ Experience in management of CROs and/or site monitoring and quality compliance;
- ✓ Knowledge of GCPs;
- ✓ Advanced computer skills including proficiency in MS Office software;
- ✓ Excellent communication and interpersonal skills;

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Job Competencies & Personal Attributes

- ✓ Autonomous and detailed oriented;
- ✓ Strong operational management skills;
- ✓ Dynamic and proactive;
- ✓ Willingness to travel internationally sometimes up to 50% of the time;
- ✓ Disciplined and very well organized;
- ✓ Persuasive and diplomatic.

The Clinical Affairs Manager will report to the Chief Development Officer. The position is based in Paris, France.
To apply to this position please email your CV to *jobs@tissium.com*

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