Clinical Affairs Manager

Xeltis is looking for a Clinical Affairs Manager to work in a dynamic research environment towards the clinical realization of Xeltis' revolutionary restorative medical devices.

The Clinical Affairs Manager is responsible for managing all aspects of Xeltis International clinical studies, ranging from first in human to pivotal studies. This includes timely completion of the study, within budget and in compliance with SOPs, applicable regulations and GCP guidelines.

The Clinical Affairs Manager will report to the Senior Clinical Operations Manager and will be based in Eindhoven, NL or (partially) home office.

Xeltis is a clinical-stage medical device company pioneering a restorative approach in cardiovascular therapy. Our technology platform is the world's first polymer-based technology designed to enable natural restoration of cardiovascular function, through a therapeutic approach called Endogenous Tissue Restoration (ETR).

Who are we looking for?

Responsibilities:

- Support site identification and selection
- Manage and oversees CROs, vendors and/or clinical sites during study start-up, enrolment, follow-up phase and close-out phase
- Prepare and file submission documents in preparation of clinical trials
- Review clinical data and manage SAE documentation and reporting
- Review interim and final reports in close cooperation with Clinical Affairs team and CRO
- Review clinical study documents (study protocol, monitoring plan, safety plan, etc.)
- Collaborate closely with the R&D, QA and Clinical Affairs teams, external consultants, vendors and CROs
- Collaborate professionally with investigators and other study site members
- Assist company non-clinical departments in meeting quality, regulatory, engineering, marketing and sales goals and objectives, as needed.
- Provide periodic updates or reports on the current status of clinical trials to senior management
- Be in charge of the overall documentation and adequacy of conduct, data quality, compliance and adherence to timelines for their assigned trial(s)
- Keep budget on track and escalate potential overspending in a timely manner
- Oversee management of study supplies and investigational product accountability

Minimum Qualifications:

- 3+ years of experience in clinical project management
- Experience with Class III medical devices – preferably implantable cardiovascular devices
- Familiar with European and US regulations, knowledge of other regulations is a plus
- Proven experience in managing First-in-Human studies or pivotal studies in the EU and US. Experience from other regions, like Asia, is a plus.
- Experience in preparing and reviewing relevant documentation for ethics committees, competent authorities and regulatory agencies in cooperation with CROs and regulatory affairs

- Ability to successfully interact with clinical sites, investigators, hospital study nurses
- Excellent communication skills and English fluency
- Strong organisational skills - ability to identify and adapt to shifting priorities and competing demands
- Ability to travel
- Ability to make timely and well-reasoned decisions
- Very strong interpersonal and motivational skills
- Strong experience using Microsoft applications (Excel, Word, PowerPoint, Outlook)

Working at Xeltis

At Xeltis, we recognize that people make a difference. We are a young, dynamic, international team of 30+ professionals dedicated to improving patients' lives through innovation.

For more information please visit www.xeltis.com; to submit your CV and motivational letter, please contact: recruitment@xeltis.com