Manager (Pre-) Clinical Affairs Eindhoven, The Netherlands

Xeltis BV in Eindhoven is looking for a Manager (Pre)- Clinical Affairs,
reporting to the VP Pre-Clinical Affairs.

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

Job Function/Activities

- Support site (pre-clinical and clinical) identification and selection.
- Manage CROs 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 and pre-clinical studies.
- Review clinical data and manage SAE documentation and reporting.
- Review interim and final reports in close cooperation with Clinical Affairs team at Xeltis and CRO.
- Collaborate closely with the R&D, QA and Clinical Affairs team, external consultants and CROs.
- Professional collaboration with investigational sites, investigators and other study site members.
- Assists as needed with Company non-clinical departments in meeting quality, regulatory, engineering, marketing and sales goals and objectives.
- Provides periodic updates or reports of the current status of (pre)-clinical trials to senior management.
- Administration - responsible for study status reports, essential documents, and accurate study files.

Knowledge and skills

- 5+ years' experience in clinical project management, experience with Class Ill medical Devices – preferably implantable cardiovascular devices.
  Previous Cardiology and Cardiac Surgery experience.
- Familiar with European and US regulations, knowledge of other regulations is a plus
- Proven experience in managing/execution Pre-clinical studies.
- Experience with First in Man 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.
- Very good communication skills with fluency in English, German is a plus.
- Ability to travel

Education

Bachelor according to Dutch education system or equivalent.

About Xeltis

Xeltis is a clinical-stage medical device company pioneering a restorative approach in heart valve therapy. Xeltis' technology enables natural heart valve restoration. Xeltis is currently investigating additional applications of its innovative approach to restore other heart valves and blood vessels.

At Xeltis, we recognize that people make a difference. We are a young, dynamic, international team of 25+ professionals dedicated to improving patients' lives through innovation.

Our Company values

We at Xeltis:

- Innovate to improve patients' lives
- Listen and challenge with respect
- Grow through personal development
- Act like owners for a common goal
- Work with JOY!

For more information and to submit your CV and motivational letter in Dutch and English, please contact Xeltis HR at: recruitment@xeltis.com