Senior Clinical Project Manager (sCPM) /Senior Clinical Trial Manager (sCTM)
Full-time, Munich, Germany

About us:

TRiCares is dedicated to bringing innovative, minimally invasive treatment solutions to patients with failing tricuspid valves. We are looking for a proactive and skilled Regulatory Affairs Manager to join our dynamic team in Munich and support us in our mission to improve patient care. Unique opportunity for practically oriented hands-on Clinical Trial Manager to join a small, expanding medical device company in Munich, Germany, where you will work closely together with the clinical affairs team. TRiCares GmbH is a manufacturer of cardiovascular medical devices for the minimally invasive treatment of tricuspid valve diseases.

Responsibilities

- Oversee clinical project management and day-to-day clinical operations throughout the entire study lifecycle, including start-up, execution, and close-out.
- Maintain in depth knowledge of protocol, therapeutic area, and indication.
- Contribute to the development and writing of clinical study documentation and processes.
- Ensure study conduct aligns with the clinical study protocol and relevant regulations.
- Serve as the primary point of contact for study sites, ensuring prompt resolution of inquiries to maintain protocol compliance.
- Support timely clinical data collection, review, and cleaning activities to ensure high data quality and resolve any discrepancies.
- Responsible for management of study vendors.
- Maintain accurate and up-to-date study documentation and Trial Master File (TMF), including the collection, administration, and tracking of essential documents.
- Support the submission of study-specific documents to regulatory authorities, including ethics committees and competent authorities.
- Conduct co-monitoring and monitoring visits, as well as other sponsor-initiated visits at study sites if required.
- Monitor study progress and provide regular updates to Clinical Affairs leadership.
- Collaborate with cross-functional teams to ensure seamless execution of clinical studies

Requirements:

- Bachelor's degree in Life Sciences, Nursing, or a related field.
- Minimum of 4 years of experience of Clinical Trial Management within the medical device industry or a Contract Research Organization (CRO), preferably with Class III devices.
- Demonstrated ability to drive clinical trial activities: i.e. experience in all aspects of study start-up and conduct, regulatory obligations, adverse event reporting etc.
- In-depth working knowledge of ISO-14155, ICH-GCP, MDR, and associated guidelines.
- Ability to work independently and manage multiple priorities.
- Experience with electronic data capture and tracking systems.
- Monitoring experience is advantageous.
- Knowledge of cardiovascular medicine is a plus.
- Strong attention to detail, with excellent organizational and teamwork skills.
- Exceptional communication abilities.
- Proficiency in Microsoft Office.
- Proficiency in English is required; German language skills are an advantage.

What We Offer:

- A dynamic and forward-thinking work environment, shaping the future of transcatheter heart valve therapy
- The opportunity to work in a truly international team, with talented and driven colleagues from around the globe
- A strong company culture rooted in collaboration, innovation, and purpose
- Excellent opportunities for personal and professional development in a fast-growing MedTech company
- A competitive compensation and benefits package tailored to your experience and contribution
- Regular team events and offsites to connect, celebrate successes, and foster team spirit
- An inclusive and respectful workplace where diversity is not only welcomed but valued

Ready to make a difference?

We look forward to receiving your application. Join us on our journey to transform patient care – one heartbeat at a time.

Apply now at: HR@tricares.de.