Regulatory Affairs Specialist
Full-time, Munich, Germany

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.

The **Regulatory Affairs Specialist** will play a crucial role in supporting the Director of Regulatory Affairs in preparing and submitting the technical file to the notified body in Europe to obtain CE mark approval for a Class III medical device.

Key Responsibilities:

- Assist in compiling and submitting the technical file to the European notified body for CE mark approval of a Class III medical device.
- Collaborate with cross-functional teams, including R&D, Quality, and Clinical, to gather the necessary documentation and evidence for regulatory submissions.
- Support the development and submission of regulatory documents for FDA clearance and approval.
- Assist in preparing the Investigational Device Exemption (IDE) submission, ensuring compliance with all relevant regulations and guidelines.
- Draft, review, and maintain regulatory documents, including Clinical Evaluation Reports, Risk Management documentation, and regulatory submission dossiers.
- Ensure accuracy, consistency, and compliance with regulatory requirements and internal standards.
- Monitor and report safety and vigilance data to relevant authorities as per regulatory requirements.
- Ensure timely reporting of adverse events and field safety corrective actions.
- Support the Director of Regulatory Affairs in developing regulatory strategies for global market access.
- Ensure compliance with relevant international standards, including EU MDR and US FDA regulations.
- Work closely with internal teams to provide regulatory guidance during product development and post-market activities.
- Communicate effectively with notified bodies, regulatory agencies, and external partners.

Qualifications and Experience:

- Bachelor's degree in Life Sciences, Engineering, or a related field. A Master's degree is a plus.
- Minimum of 3 years of experience in regulatory affairs within the medical device industry, preferably with Class III devices.
- Experience with CE mark submissions under EU MDR; familiarity with FDA regulatory pathways, including IDE submissions, is an advantage.
- Proven experience in writing and reviewing regulatory-relevant documents.
- Knowledge of safety and vigilance reporting requirements in Europe.
- Excellent organizational, communication, and problem-solving skills.
- Proficiency in English is required; German language skills are an advantage.

What We Offer:

A dynamic and innovative work environment with opportunities for professional growth.
Collaboration with a highly skilled and passionate team in a truly multinational company, with colleagues from all over the world.
Competitive salary and benefits package.

How to Apply:

Interested candidates are invited to submit their CV and a cover letter detailing their relevant experience and motivation for the role to Omeragic@tricares.de.