Senior Regulatory Affairs Manager (EU MDR, Class III)
Full-time, Munich, Germany

TRiCares is dedicated to bringing innovative, minimally invasive treatment solutions to patients with failing tricuspid valves. We are a fast-growing medical device company developing a Class III implantable device and operating in a dynamic, international environment.

We are looking for a Senior Regulatory Affairs Manager to join our Regulatory Affairs team in Munich and play a key role in driving EU MDR compliance and CE marking activities.

The **Senior Regulatory Affairs Manager** will play a key role in driving the preparation, maintenance and submission of the EU MDR technical documentation to the Notified body to obtain CE mark approval for a Class III medical device. The role reports to the Director of Regulatory Affairs and contributes actively to regulatory strategy and execution.

Key Responsibilities:

- Independently prepare and maintain submission-ready EU MDR technical documentation supporting CE marking submissions to the European Notified Body. Ensure documentation is complete and consistent.
- Support and participate in interactions with Notified Body and regulatory authorities, including preparation of documentation and responses.
- Draft, review and maintain regulatory documents, including Clinical Evaluation Reports, Risk Management documentation, and regulatory submission dossiers.
- Ensure accuracy, consistency and alignment between clinical, risk and regulatory documentation.
- Collaborate with cross-functional teams, including R&D, Quality, and Clinical, to gather the necessary documentation and evidence for regulatory submissions.
- Work closely with internal teams to provide regulatory guidance during product development and post-market activities.
- Actively contribute to and support the execution of regulatory strategies for global market access. Support assessment of regulatory impact for design, clinical and manufacturing changes.

Qualifications and Experience:

- Bachelor's degree in Life Sciences, Engineering, or a related field. Master's degree is a plus.
- Minimum of 5 years of Regulatory Affairs experience in the medical device industry, preferably with Class III devices.
- Hands-on experience with EU MDR technical documentation and Technical file compilation is required, as well as experience with CE mark submissions.

- Strong experience in drafting and critically reviewing regulatory documents.
- Experience in cardiovascular or implantable medical devices is a plus.
- Familiarity with FDA regulatory pathways (e.g. IDE, PMA) is an advantage.
- Proven ability to work autonomously and manage regulatory documentation with minimal supervision.
- Excellent organizational, communication, and problem-solving skills.
- Proficiency in English required; German is an advantage.

What We Offer:

- A dynamic and innovative work environment with significant responsibility and direct impact on bringing a Class III medical device to market.
- High level of autonomy within a growing Regulatory Affairs team.
- Close collaboration with highly skilled and passionate team and cross-functional experts in an international work environment.
- 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 HR@tricares.de