



Quality and Regulatory Affairs Manager

Full-time, Munich, Germany

Company Overview:

TRiCares is dedicated to bringing innovative, minimally invasive treatment solutions to patients with failing tricuspid valves. We are looking for a proactive and skilled Quality and Regulatory Affairs Manager to join our dynamic team in Munich and support us in our mission to improve patient care.

Unique opportunity for a QA/RA Manager to join an agile, expanding medical device company in Munich, Germany. TRiCares GmbH is a manufacturer of cardiovascular medical devices for the minimally invasive treatment of tricuspid valve diseases.

Position

The role involves tasks such as

- Maintain and improve the existing Quality Management System Accord. To ISO 13485:2016 through existing improvement processes (CAPA and others)
- Implementing US-QMSR into our QM System
- Plan and conduct Process Validation activities in cooperation with our critical suppliers
- Plan and conduct internal and supplier audits
- Supplier quality management

Key Responsibilities:

Responsibility 1: Process Validation responsible.

Responsibility 2: supplier management

Qualifications and Experience:

- At least 4 years experience in quality management in a medical device company, ideally with class III implantable devices.
- Excellent communication skills, both written and verbal in English; proficiency in other languages is advantageous (e.g. Portuguese)
- Experience with R&D / QM interfaces
- Strong organisational and analytical skills
- Ability to work in a fast-paced and dynamic environment
- Proficiency in MS Office applications: Excel, PowerPoint, and Word.

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 pinkowski@tricare.de.