

## **Customer Quality Manager (all genders)**

Full-time · On-Site · Munich, Germany

### **About us:**

At TRiCares, we are dedicated to providing innovative, minimally invasive treatment solutions for patients suffering from failing tricuspid valves. As a growing MedTech company, we are looking for an experienced Customer Quality Manager to join our team in Munich and support our mission to improve patient care.

In this role, you will ensure that product quality and safety information from the field is systematically captured, investigated and translated into effective quality actions. Reporting to the Head of QA/RA, you will work closely with Regulatory Affairs, Product & Design Quality, R&D, Clinical/Medical Affairs and Supplier Quality to support product safety and continuous improvement. You will also establish a vigilance and medical device reporting system for the EU and US in preparation for the market approval of TRiCares products.

### **Responsibilities**

- Own and manage the complaint handling process for medical devices marketed in the EU and US, ensuring timely intake, documentation, investigation, evaluation, closure and follow-up.
- Lead and coordinate complaint and quality issue investigations, including information gathering, product returns and evaluation, review of manufacturing and quality records, root cause analysis and documentation of conclusions.
- Assess complaints for regulatory reportability in accordance with applicable EU and US requirements and internal procedures.
- Work closely with risk management to assess complaint findings and determine whether existing risk management files require updates.
- Coordinate and ensure the timely submission of vigilance and regulatory reports to competent authorities and the FDA, collaborating with Regulatory Affairs as applicable.
- Evaluate complaints for potential patient and user safety risks, product deficiencies and the need for field actions or recalls, escalating critical cases in line with established procedures.
- Maintain complete, accurate and inspection-ready complaint records in accordance with regulatory requirements and the company's Quality Management System (QMS).
- Analyse complaint data and trends to identify recurring issues, emerging safety signals and adverse trends, and communicate findings to Quality, Regulatory Affairs, R&D, Manufacturing and Management.
- Ensure complaint information feeds into risk management, post-market surveillance (PMS), Post-Market Clinical Follow-up (PMCF), periodic safety reporting, product improvement and CAPA processes, as applicable.
- Serve as the subject-matter expert for complaint handling during internal and external audits and regulatory inspections, including preparing complaint files and responding to auditor and authority requests.
- Develop, maintain and continuously improve complaint handling procedures, work instructions, templates and key performance indicators (KPIs).

## Requirements:

- A bachelor's degree or higher in engineering, life sciences, biomedical sciences or a related technical discipline.
- Significant experience in medical-device Quality Assurance, preferably involving high-risk or Class III devices.
- Demonstrated experience in complaint handling, investigations, vigilance and adverse-event assessment, and post-market quality.
- Strong knowledge of applicable medical-device quality and post-market regulatory requirements, including working knowledge of ISO 13485, ISO 14971, EU MDR post-market and vigilance requirements, and applicable FDA quality and reporting requirements.
- Experience supporting regulatory inspections and/or notified-body audits.
- Experience with CAPA, root cause investigations, risk management and quality-data trending.
- Experience in technical and scientific writing.
- Strong analytical skills and a structured, risk-based approach to identifying and resolving quality and regulatory issues.
- Excellent communication and collaboration skills, with the ability to work effectively with senior management, internal departments, external partners, auditors and regulatory stakeholders.
- A very good command of written and spoken English.

## Why You'll Enjoy Working With Us:

- 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 growth in a fast-growing MedTech company, including annual training and development opportunities.
- A competitive compensation tailored to your experience and contribution and attractive benefits, including Wellpass, Corporate Benefits, a referral bonus, employee parking, and your choice of either a "Deutschlandticket" subsidy or JobRad
- 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@tricare.de](mailto:HR@tricare.de).