Medical Device Safety Officer (all genders)
Full-time · On-site · Munich, Germany

About us:

At TRiCares, we are dedicated to developing innovative, minimally invasive solutions for patients with failing tricuspid valves. As a growing MedTech company based in Munich, we are seeking a highly motivated and experienced Medical Device Safety Officer to support our mission of improving patient care through safe and compliant medical device development.

This is a unique opportunity to join a fast-growing medical device company and contribute within a passionate, international team working to transform cardiovascular treatment through innovative technology.

We are seeking a Medical Device Safety Officer to join our Medical & Regulatory organization, reporting to the Vice President Medical & Regulatory Affairs. In this pivotal role, you will be responsible for establishing, managing, and continuously improving safety-related processes. Working closely with Clinical Affairs, Regulatory Affairs, R&D, Quality, and external partners, you will ensure compliance with global regulatory requirements and contribute to the safe advancement of innovative heart valve technologies.

Key Responsibilities:

- Lead and manage medical device safety and vigilance activities in compliance with applicable regulations and standards (FDA, EU MDR, ISO 14155, GCP).
- Oversee the collection, assessment, documentation, and reporting of adverse events, device deficiencies, and safety signals.
- Prepare, review, and submit safety reports, medical device alerts, field safety notices, and vigilance documentation to regulatory authorities and ethics committees.
- Serve as the primary point of contact for safety-related inquiries from investigators, regulatory agencies, ethics committees, and internal teams.
- Organize and lead safety review activities, including Clinical Events Committee (CEC) and Data Monitoring Committee (DMC) meetings.
- Support clinical trials by training investigators and study staff on safety reporting requirements and procedures.
- Collaborate with Clinical Affairs, R&D, and Quality to assess device-related risks, implement mitigation strategies, and support protocol amendments related to safety.
- Prepare for and participate in safety-related audits, inspections, and regulatory interactions.
- Monitor safety performance of investigational devices and drive continuous improvement of safety processes in line with quality system requirements.
- Manage safety activities in alignment with defined timelines, budgets, and project milestones.

Qualification and Experience:

- Scientific degree in a relevant field (e.g. life sciences, biomedical engineering) or equivalent clinical experience
- Strong knowledge of cardiovascular science, valvular heart disease, and medical device clinical trials
- Proven experience in medical device safety reporting, vigilance activities, and interaction with regulatory authorities
- Solid understanding of applicable regulations and standards, including ISO 14155, FDA CFR, EU MDR, and Good Clinical Practice (GCP)
- Excellent written and verbal communication skills in English; ability to work independently as well as collaboratively in cross-functional teams
- Experience in interventional cardiology, cardiac cath lab, or hybrid OR environments
- Demonstrated experience in teaching, training, and presenting clinical or medical information to healthcare professionals
- Willingness to travel up to 50% and ability to work in clinical environments, including exposure to radiation and non-standard working hours

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.