

Operations Engineer (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 in Munich, we are seeking a proactive and skilled Operations Engineer to support our mission to improve patient care.

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 highly motivated Operations Engineer to join our heart valve Operations team, reporting to the Head of Operations. In this pivotal role, you will contribute to the realization of innovative heart valve technologies by developing, improving, and supporting key manufacturing processes. Working closely within a multidisciplinary team, you will help advance cardiovascular devices from clinical trials to commercialization by optimizing workflows, strengthening manufacturing capabilities, and providing essential technical expertise.

Key Responsibilities:

- Manage and optimize manufacturing systems and processes to improve efficiency, quality, and productivity, including oversight of Incoming Goods Inspection (IGI).
- Troubleshoot operational and equipment issues, perform root cause investigations, and implement permanent corrective and preventive actions.
- Monitor and analyze process and quality performance data to identify and drive improvements in efficiency, reliability, and cost-effectiveness.
- Lead workflow optimization and automation initiatives to enhance operational robustness and reduce manual effort.
- Plan, execute, and document validations for equipment, processes, and systems.
- Prepare and maintain comprehensive technical documentation (test protocols/reports, FMEAs, risk assessments, design inputs/outputs, and change records).
- Ensure adherence to safety, regulatory, and quality standards, including ISO 13485 and FDA 21 CFR 820.
- Collaborate with cross-functional teams to resolve issues, support decision-making, and strengthen manufacturing capabilities.
- Interface with suppliers and external partners for component development, tooling, qualification, and issue resolution.
- Support product development across all phases—from concept and prototyping to verification & validation, design transfer, and sustaining engineering.
- Evaluate new technologies and manufacturing methods to improve product performance and manufacturability.
- Create clear reports and documentation on operational performance, quality findings, and improvement initiatives.

Qualification and Experience:

Required

- Bachelor's or Master's degree in Biomedical Engineering, Mechanical Engineering, or a related field
- 2+ years of experience in medical device R&D or manufacturing (structural heart or implantable devices preferred)
- Strong analytical, troubleshooting, and problem-solving skills
- Familiarity with biomaterials, mechanical testing, and process characterization
- Proficiency in Python or shell scripting and good understanding of technical systems
- Excellent communication, documentation, and project management skills
- Ability to work collaboratively in a dynamic, fast-paced environment with high attention to detail

Preferred

- Knowledge of regulatory standards (ISO 13485, ISO 14971, ISO 5840, FDA 21 CFR 820)
- Experience with statistical tools (e.g., Minitab), DOE, and Six Sigma methodologies

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.