Quality & Design Assurance Engineer (80–100%)

Bern, Switzerland | 80-100% | On-site

LEM Surgical AG is an innovation-driven MedTech company based in Bern, Switzerland. We are redefining spine surgery by developing a next-generation surgical robotic system. It combines high-precision mechanics, advanced software, and intelligent system integration in a safety-critical clinical environment.

We are looking for a Quality & Design Assurance Engineer who supports quality processes throughout product development and manufacturing. In this role, you will work closely with engineering, manufacturing and quality teams to ensure that design changes, product documentation and manufacturing processes meet regulatory and quality requirements. You will contribute to design transfer activities, help resolve quality issues and continuously improve our processes as we grow.

Your Responsibilities

- Coordinate engineering change orders (ECOs), working with different teams to assess changes and ensure they are properly reviewed, documented and implemented.
- Maintain product data in SolidWorks PDM and ensure consistency of drawings, bills of materials (BOMs) and master data across our engineering and ERP systems.
- Support design transfer activities in New Product Introduction (NPI) projects, ensuring that manufacturing documentation is complete and products are ready for production.
- Investigate nonconformities (NCs) and support CAPA activities, including root cause analysis, corrective actions and effectiveness checks.
- Work with Procurement on supplier quality activities, including supplier qualification, performance monitoring and the resolution of quality issues.
- Coordinate equipment calibration, maintenance and qualification, as well as process, test method and computer system validation activities.
- Support product labeling activities, including GTIN and UDI requirements, and contribute to risk management in accordance with ISO 14971.
- Maintain and improve quality documentation, including SOPs, work instructions and quality records, and support internal and external audits.
- Identify opportunities to improve quality processes and make our daily operations more efficient.

Your Profile

- A bachelor's or master's degree in Mechanical Engineering, Biomedical Engineering or a related technical field.
- At least 3 years of experience in Quality Engineering, Design Assurance or a similar role, ideally in the medical device industry.
- Good understanding of quality management systems and relevant standards such as ISO 13485, FDA QMSR (21 CFR Part 820) and ISO 14971.
- Practical experience with engineering change control, nonconformities, CAPAs or other quality processes in a regulated environment.
- Familiarity with PDM/PLM or ERP systems. Experience with SolidWorks PDM or Odoo is an advantage.
- A structured and hands-on working style, with an interest in both technical development and manufacturing processes.
- A proactive mindset, attention to detail and the motivation to learn and take on new responsibilities.
- Strong communication skills and the ability to collaborate effectively with colleagues across different teams.
- Fluent English, both written and spoken. German is a plus.

What we offer

- The opportunity to contribute to innovative surgical robotics technology and make a real impact on the future of surgery.
- A varied role that allows you to develop your expertise across quality engineering, product development and manufacturing.
- The opportunity to take responsibility, contribute your ideas and grow professionally as the company develops.
- Close collaboration with experienced engineers and specialists across different disciplines.
- An international and collaborative team in a dynamic startup environment where your contribution makes a difference.

Interested in joining us?

We would love to hear from you! Send your application to **careers@lemsurgical.com** or learn more about us at **www.lemsurgical.com**.

We look forward to receiving your application!