



LEM Surgical AG is a dynamic and pioneering high-tech MedTech startup based in Bern, Switzerland. We are at the forefront of developing the next generation of spine surgical robots. As we continue to grow and advance our cutting-edge technology, we are seeking a motivated recent graduate to join our team as a QA/RA Associate. In this crucial role, you will contribute directly, helping to shape the future of spine surgery.

QA/RA Associate

Your responsibilities

- Collaborate closely with product development and operation teams.
- Monitor priorities, track progress against schedules, and communicate status updates to other departments.
- Assist in the implementation and regulation of ISO and FDA requirements.
- Support Regulatory Affairs in creating submissions and responding to submission inquiries.
- Participate in internal and external audits, including preparation and direct interaction with auditors.
- Work cross-functionally to resolve technical issues.
- Author technical or quality management system documents with clarity, detail, and correctness.

Your Profile

- **Minimum qualifications:** BSc. in Bioinformatics, Biomedical Engineering, or an equivalent degree.
- **Experience:** At least 1 year of experience in Quality Engineering or a related field within the medical device industry.
- Strong attention to detail and excellent communication skills.
- Capable of effectively communicating complex information to teams and management.
- Ability to quickly learn and apply medical standards such as ISO 13485, ISO 14971, and FDA Quality System Regulations, particularly in design controls and optimization.
- Familiarity with FDA guidance documents, as well as ISO and ASTM standards related to quality and the medical device industry.
- Experience or knowledge of design control and risk management from early design and development through commercialization is an advantage.
- Knowledge, experience, or a strong understanding of FMEAs, Root Cause Analysis, CAPAs, Non-Conformance management, and Process Validation.

Start date

- As soon as possible or by agreement.

Join LEM

In this role, you'll gain hands-on experience in a fast-paced environment with the opportunity to learn from leaders and grow your career in MedTech.

At LEM Surgical AG, we foster a collaborative and innovation-driven culture where every team member plays a crucial role in shaping the future of surgery. Your contributions will directly impact patient outcomes and drive advancements in medical technology.

Ready to shape the future of surgical robotics with us? Apply today and take the next step in your career by joining a team that's making a real difference in medical technology.

