QARA Engineer for Lymphatica Medtech

Lymphatica Medtech SA

Lymphatica Medtech is a pioneer in implantable systems for lymphedema treatment. Spin out of EPFL and CHUV in 2017, the growing company has received national and international recognitions for its breakthrough approach.

We work in a competent and motivated team, implementing an ambitious project to have a significant impact for lymphedema patients and society as a whole.

Job Summary

The QARA Engineer will play a key role in the Quality and Regulatory Affairs Department, ensuring that our products comply with all relevant national and international regulations.

Lymphatica's products are currently in pre-market phase and the QARA Engineer will actively contribute to the core activities of the Quality and Regulatory Affairs Department and will collaborate with the other company departments towards a successful product launch in selected European markets and in the US.

The job location will be Lausanne (Switzerland), with possibility of partial remote working.

Responsibilities

- Support: Assist the Quality and Regulatory Affairs department in its business activities, including document preparation (SOPs, templates, records).
- Regulatory Pathway Facilitation: Help facilitate the regulatory approval process for new products.
- Quality Management: Contribute to the establishment and maintenance of an electronic Quality Management System (QMS) compliant with ISO 13485 and 21 CFR Part 820 (current versions).
- Cross-Department Collaboration: Work closely with other departments such as R&D, Clinical, and Sales & Marketing to ensure regulatory and quality requirements are met.
- Regulatory Updates: Stay informed on national and international regulations and standards in the medical device field.
- Audit Participation: Participate in internal and external audits to ensure compliance.
- Authority Engagement: Take part in meetings with competent authorities (in EU and U.S).
- Regulatory Submissions: Contribute to regulatory submission processes, including the preparation and revision of technical reports.

Qualifications & Skills

- Engineering diploma,
- At least 2 years of experience in Quality and Regulatory Affairs for medical devices,
- Knowledge of ISO 13485:2016 and 21 CFR Part 820,
- Excellent communication, organizational, and documentation writing skills,
- Ability to work in an interdisciplinary team,
- Proficient written and verbal communication in English,
- Experience with Class 3 devices is a plus,
- Experience in submissions to competent authorities is a plus,
- Previous experience in regulatory support for the development of medical device SW is a plus,
- Experience with risk management according to ISO 14971 is a plus.

How to apply

- Please submit your CV and cover letter to vicky.boucard@lymphatica.ch.
- We look forward to reviewing your application!