

QM/REGULATORY AFFAIRS - WORKING STUDENT (m/f/d)

LARALAB's goal is to revolutionize the planning of cardiac interventions and improve the lives of patients worldwide. We are developing cloud-based planning software powered by deep learning technology to support the innovation of new, minimally invasive cardiac procedures, and to make these procedures available to patients in need. We have collaborations with leading clinics and medical companies, and are backed by strong investors.

Would you like to play a role in this growth process? We are looking for a **Quality Management** / **Regulatory Affairs Working Student** to join our team of medical and software experts. You will contribute to the development and regulatory approval process of our impactful software products, with the goal of making them available to patients. You will work closely with Quality Management, Regulatory Affairs and Software Development in an exciting position.

Your Skills

- Analytical and structured working style with ability to quickly adapt to new topics and take over responsibility
- Interest in learning about regulatory affairs and certification of medical device software, including CE marking and FDA approval.
- Basic knowledge and understanding of the regulatory frameworks and relevant standards for medical software (e.g. IEC 62304, ISO 14791)
- High level of self-motivation, flexible mindset, ability to adapt in fast-paced environment and proactive in finding solutions
- Passion in medical devices, cutting edge medical technology and artificial intelligence

Your Challenges

- Support software releases and compile technical documentation for regulatory submissions for our AI-based software products (e.g. FDA 510(k), MDR)
- Ensure compliance with standards applicable to medical device software development.
- Perform software testing.
- Support on audits and inspections by regulatory authorities.

Be Part of Our Story – there is a lot in it for you!

- Opportunity to grow in an international company which provides a real purpose
- Dynamic start-up environment with a young, passionate, and skilled team
- Be part of the Quality Team and contribute to the improvement and development of our software
- Steep learning curve, great working environment, office centrally located in Munich
- Flexible schedule that accommodates to a busy-student-life

Sounds interesting? Send us your CV, cover letter, and relevant certificates. Have questions? We'll be happy to answer them!

jobs@laralab.de



