REGULATORY AFFAIRS & QUALITY SPECIALIST (m/f/d)

At Laralab, we are a start-up working on exciting and impactful things! Our goal is to make the planning of cardiac interventions more thorough and to help introduce new therapy options with better outcomes. We have partnerships with companies and clinics worldwide and are backed by strong investors. We love the challenge of innovation and our technologies are A.I.-powered (truly!). Most of all, we are growing our team to make these innovations a growing reality.

Would you like to play a central role in this growth process? We are looking for a **Regulatory Affairs and Quality Specialist** to join our team of medical and software experts. You would be contributing to the Regulatory Affairs and Quality Management team and managing the technical documentation of our products.

Your Skills

- Degree in life science, engineering, (medical) informatics, medicine or equivalent
- Initial professional experience in Regulatory Affairs and certification of medical device software
- Initial professional experience in Process and Quality Management
- Basic knowledge of laws, standards and regulations for licensing medical devices and for business processes of medical device manufacturers (e.g. MDR; 21CFR 820; ISO 13485; IEC 62304; IEC 62366; ISO 14971)
- Knowledge of the FDA approval process for medical devices is a plus
- High level of self-motivation, team-working attitude, flexible and client-oriented mindset, ability to adapt in a fast-paced environment and proactive in finding solutions

Your Challenges

- Maintain and improve processes within our Quality Management System to comply with ISO 13485 and 21CFR 820
- Support Regulatory Affairs actions to file for CE certification and FDA approval
- Contribute to audits and inspections by regulatory bodies
- Support the team with regulatory strategies for AI-based products
- Ensure compliance with standards applicable to medical device software development

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

- Opportunity to grow with an international company which provides a real purpose
- Be part of the Regulatory Affairs and Quality Managementteam and contribute to the regulatory clearance of the products
- Steep learning curve, great working environment, office centrally located in Munich

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

jobs@laralab.de