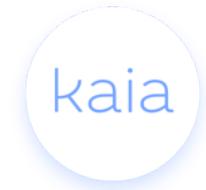


Head of Regulatory Affairs

Regulatory Affairs | Munich, BY, Germany



Kaia is a mission focused medical technology company

In 2016 we set out with the mission to make effective, evidence-based therapies available to patients who suffer from chronic diseases. As back pain is the number one cause of disability worldwide with over 1 billion affected people, we built our first product, a clinically-proven mind-body therapy app, to help people with back pain.

The role encompasses:

Today we have more than 250.000 users across multiple apps and deployments. We are in the market as with two stand-alone software solutions regulated as medical devices in the EU and have a certified QM system according to ISO 13485 since 2016.

- You will interact with the Tech team, the Medical team and external advisors to set up proper technical documentation of Kaia's products for regulation in the EU and USA
- You take ownership of the international regulatory strategy for Kaia's products together with the Chief Technical Officer and the Chief Medical Officer
- You take ownership of Kaia's Quality Management System to make processes compliant with EU and US/FDA regulations
- You make sure that the individual teams work according to relevant medical device manufacturer regulations in cooperation with team leaders

Your profile:

- 3+ years experience in regulatory affairs for medical devices, preferably in stand-alone software as a device and knowledge of all applicable standards in EU and USA
- Experience with Quality Management Systems compliant with the ISO 13485, ideally also compliant with 820 CRF part 21
- Ability to own regulatory processes at the interface of development, clinical and business teams
- Systematic problem-solving approach, coupled with strong english writing skills and a sense of ownership and drive

Ideally you also have:

- Experience in small and scaling enterprises
- A university degree in a relevant area
- Understanding of the most fundamental machine learning concepts

You'll fit in with our company culture if you also:

- view technology as a tool to improve a user's life
- have a bias for action; the world is complex and unpredictable place so starting, releasing fast, and getting feedback iteratively is the only possible path to success
- strive to be articulate and humble, make the complex, simple, present ideas openly, accepting that being wrong is part of the process
- thrive in an entrepreneurial team, adapt easily to change, and enjoy a fast-paced environment

Some of the benefits we offer:

- Directly shape the future of digital health with competitive salary
- A workplace in the city center of Munich with good connections or remote working possible
- Flat hierarchies, flexible vacation and working times