

For our team in Munich, we are currently looking for a

Quality Engineer (m/f/d)

Industry: Medical Devices

Location: Munich, Germany

Employment: Full-time position

Qualifications: Bachelor's or Master's degree in engineering or life science;
Experience in quality management or regulatory affairs in the medical device field;
Excellent verbal and written English skills

Your role

As Quality Engineer, you will be part of the team for Quality Management and Regulatory Affairs. As an all-rounder, you will support the development, production, and servicing of our innovative biomedical imaging devices. Your work influences the quality of our product and ensures the market access.

You will get exposure to all core quality processes of the company's ISO 13485-certified quality management system as a medical device manufacturer and your responsibility will cover the entire lifecycle of our products. You will have responsibility for the quality processes and their implementation. Where needed you will improve them to ensure that they are state-of-the-art.

Teamplay and communication are key, as you will support other teams such as Service, Production, Sales, and Applications to achieve compliance most effectively. Furthermore, you will help the Quality team to keep the quality management system lean and effective by identifying and understanding new regulatory requirements as well as maintaining and improving the digital tool landscape for quality management.

Principal duties and responsibilities include the following:

- Ensure compliance of all core quality processes
- Support internal audits and reviews to improve core quality processes
- Support the R&D team in the creation of regulatory-compliant device documentation
- Design and development of system, hardware, and software test procedures
- Support of verification and validation of medical software
- Ensure compliance of all necessary documentation
- Support the training of colleagues on quality processes
- Maintain and improve the tool landscape used for quality-related processes
- Support the Service and the Applications teams in managing complaints and CAPAs
- Maintenance and improvement of the digital tool landscape for quality management

Your qualifications / profile

Particularly preferred skills/experience include the following:

- A degree in engineering or life sciences preferred, but other degrees may be considered
- Experience in quality management or regulatory affairs for medical devices
- Good knowledge of medical device-related regulatory requirements (ISO 13485, CFR, IEC 62304, ISO 14971, etc.)
- Excellent English communication skills, both written and verbal
- Excellent skills in general office SW, basic SW programming skills appreciated
- Structured and self-motivated way of working
- A “hands-on” and “can-do” attitude
- Ability to actively communicate and present content to mixed audiences

In addition to the skills listed above, we require a passion for exploring new grounds, developing an innovative product and working closely in a multidisciplinary international environment.

We offer

- Breakthrough technology in the growth market of medical devices
- Leading role establishing a state-of-the-art IT Infrastructure for a mid-sized start-up
- Substantial individual responsibility and the opportunity to realize own ideas
- Flexible working hours and remote work
- A young, dynamic and diversified team to work and have fun with

About iThera Medical

iThera Medical offers the next generation in photonic molecular imaging technology. The company was founded in 2010, as a spin-off from the Helmholtz Center Munich. Together, we pursue the further development of proprietary optoacoustic imaging technology for use in preclinical and clinical applications. Our international customers include the most prestigious research centers, academic hospitals and pharmaceutical companies. Please visit our website for more information (www.ithera-medical.com).

Do you want to take on responsibility and help us shape a leading-edge technology in a dynamic environment? Then we are looking forward to hearing back from you!

Applications in German or English welcome.

If you have any questions, please contact us:

Contact: Ingmar Thiemann

Email: ingmar.thiemann@ithera-medical.com