

FSQ Expertise makes innovative technology safer!

FSQ Experts GmbH offers medical technology companies precise and pragmatic solutions to overcome know-how or resource bottlenecks in the areas of quality management, regulatory affairs or system engineering.

Our customers manufacture innovative medical devices where megatrends such as robotics, AI technology and IoT play an important role. With our hands-on support, we promote a systematic approach for mastering complexity. We contribute to the certification of safe medical devices while at the same time, we manifest and expand a quality and safety culture in these companies.

To expand our team of experts we are looking for a

Technical Senior Consultant (Medical Devices) (m/f/d)

How do you contribute to the FSQ Experts team?

- You actively support the development of innovative and complex medical devices by consulting and engineering over the entire product lifecycle.
- You use your in-depth knowledge of product development, both in the V-model and in agile frameworks.
- You enable the customer to comply with the standards of the IEC 60601-x series as well as IEC 62304.
- You contribute to the implementation of general safety and performance requirements in accordance with global medical device regulations.
- You will coordinate and review technical documentation.
- You empower the customer's teams through your activities as a technical advisor, process developer, facilitator or coach.

How do we contribute for safer technology together?



Compliance with product safety standards



Establishment of safety and quality culture



Qualifications of customer's team



Smooth certification

Be part of our Team!

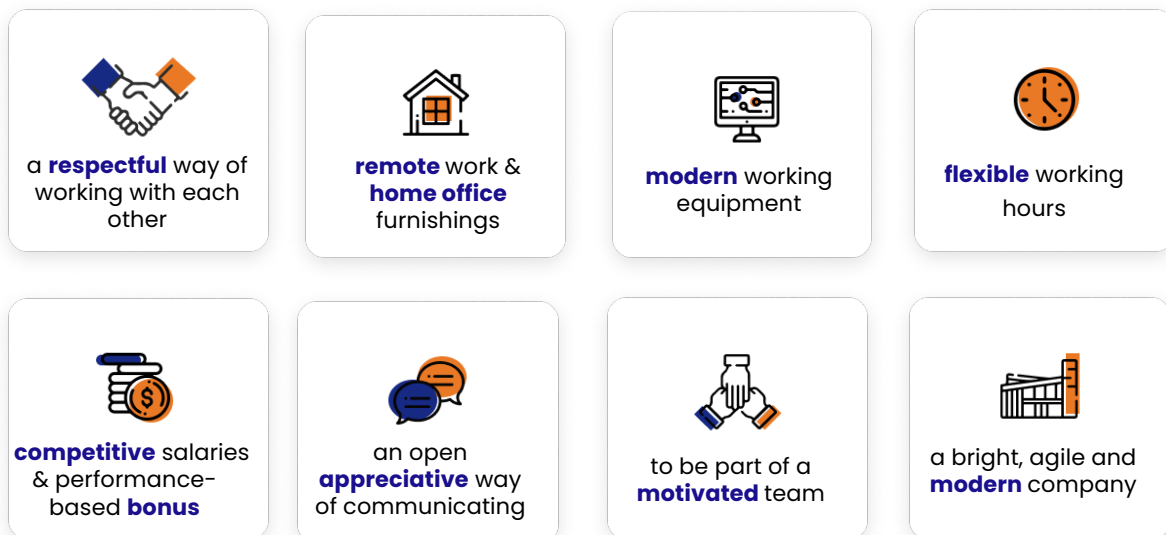
Required qualifications and technical skills:

- Relevant experience as a technical consultant
- Many years of involvement in the technical development of medical device products
- Very good knowledge of HW and SW standards for medical devices (e. g. IEC 60601-x series, IEC 62304)
- A risk-oriented mindset (according to ISO 14971) and prior knowledge of regulatory requirements worldwide (e. g. MDR, FDA)
- Familiarity with working environments compliant with ISO 13485 and ISO 9001 quality management system.

Required soft skills and mindset:

- Pragmatic, structured, communicative and service-oriented; willing to support and empower different types of customers
- Curious and willing to contribute to expanding FSQ's knowledge base in areas such as cybersecurity and artificial intelligence
- Self-organized with excellent project and time management skills; able to support different projects in parallel
- Business fluent in German and English (both at least level C1)

Make FSQ your new workplace



When will we meet?

We look forward to receiving your application (CV + motivation letter) via recruiting@fsq-experts.com. Please let us know your earliest possible starting date and your salary expectations. If you have any questions, please contact us on **+49 (0) 89 588 087 570**. We look forward to getting to know you!

Join us to make technology safer for humans!