FSQ Experts make technology safer for human beings!

Why does FSQ Experts exist?

1. We really care for safety of the human beings.
2. We contribute to make technology and products much safer.
3. We empower companies, their decision makers and engineers by coaching, consulting, training and expert level engineering.
4. We create systematically a company-wide safety and quality culture in hearts and minds.

Our customers are developers of high-end medical devices. They want to place safe and high-quality products on the market on time and within budget. We support them by raising the quality of development processes and by enhancing the know-how of project teams towards a level of sustainable regulatory compliance. We place very high demands upon ourselves with regard to technical competence and customer satisfaction.

To expand our team of experts we are looking for a

Regulatory Affairs Consultant (Medical Devices)

Join our FSQ Experts team if you…

- hold an excellent degree in engineering or another relevant field and have more than 5 years first-hand work experience in consultancy for RA & QM for Medical Devices.
- have regulatory experience with all classes of devices.
- have experience with FDA, Health Canada, NMPA.
- have strong knowledge of MDD/ MDR and IVD/ IVDR.
- provide regulatory input to new product developments and product lifecycle planning for our customers.
- actively support the development of multi-country regulatory strategies for medical devices.
- support and review regulatory submissions to authorities.
- have experience working with other medical standards (e.g. ISO 13485, ISO 14971).
- are fluent in German and English (C1 level) or are currently studying to achieve this level.

You are most welcome in our FSQ team if you …

- have alignment with the company's mission and work well in a team environment.
- have the ability to work autonomously with a positive mind set.
- are self-organized and self-motivated.
- are communicative and service oriented, willing to support and empower a wide variety of clients from small start-ups to large multi-nationals, able to adapt to different company cultures and situations.
- are pragmatic, enjoy a mix of activities in regulatory affairs, quality assurance, clinical affairs, technology and business processes.
- are willing to train team members on-the-job to become RA experts.
- are an effective team builder and problem solver, exhibiting a collaborative management style and the ability to bring out the best in people through example.
- want to empower our customers to establish processes for compliance and certification by assisting in the development and improvement of Quality/Regulatory processes.
- enjoy traveling from time to time and being involved in customer projects in Germany, Europe, and world-wide.

With FSQ as your new workplace in Munich you can expect …

- a respectful way of dealing with each other.
- an open appreciative way of communicating.
- a bright, agile and modern company.
- flexible working hours and the possibility of home office.
- a permanent contract.
- cutting edge projects in the medical device industry.

When do we meet?

We look forward to hearing from you at *contact@fsq-experts.com* or *+49 (0) 89 588 087 572*, so that we can arrange a personal meeting. Feel free to let us know about your earliest starting date and your salary expectations.

Join us to make technology safer for human beings!