

Quality & Regulatory Affairs Specialist f/m/d

XUND is a leading digital health scale-up that enables healthcare companies to digitize patient interactions and translate data into actionable insights.

It's our vision to improve the quality and accessibility of healthcare by bringing together medicine, technology and a human-centered mindset. But we cannot do it alone: we need leaders, doers, and innovative minds to turn our vision into reality.

That is why we are looking for an ambitious, highly committed and entrepreneurial individual who shares our **values of purpose, openness, courage, collaboration and integrity** and can contribute to our growth and long-term success.

Your Responsibilities

- Maintain and improve our quality management system according to ISO 13485 and the Medical Device Regulation (MDR)
- Support the product development compliant with the Medical Device Regulation (MDR)
- Work closely with the development team in designing agile development processes while ensuring compliance with regulatory requirements
- Keep the technical file of our medical devices up-to-date and communicate with authorities accordingly
- Support the quality team in internal and third-party audits
- Ensure overall compliance with national and international regulatory requirements

Your Profile

- Degree in a relevant field (e.g. life sciences, law, engineering) or equivalent industry experience
- Knowledge of the relevant standards for software as a medical device (IEC 62304, ISO 14971, IEC 62366, etc.)
- Technical understanding, love for innovative apps or software development and experience working in agile environments
- Experience with audits and Notified Bodies
- Curious, problem-solving mindset and interest in gaining new knowledge
- Excellent written and verbal communication skills in English

Nice to have

- Knowledge of the medical device industry
- Experience with Atlassian products (e.g. Jira, Confluence)
- Basic knowledge of information security management systems (ISMS)
- Experience with FDA and MDSAP audits
- Proficiency in Hungarian or German language

Your Benefits

- Become part of one of the fastest growing digital health scale-ups in Europe

- Challenging tasks in a highly innovative and dynamic environment
- Dedicated training budget and additional personal development time slots to help you build your skills
- A lively, open corporate culture with flat hierarchies and short communication channels
- Work wherever and whenever you want – at home, in the café around the corner, or in our offices in Vienna and Budapest
- Regular team events per office, as well as a few joint events per a year
- Office dogs, which (mostly) contribute to a relaxed working atmosphere

The minimum salary for this position is according to the [IT collective agreement](#) (EUR 3.077 gross monthly salary for full-time employment). Willingness to overpay is given and depends on the respective qualification and experience. On top of that, we also let all our employees participate in our Virtual Stock Option Plans (VSOPs).