

Regulatory and Quality Manager (m/f/d)

microphotonX GmbH is a biotech start-up in the south of Munich. We develop and distribute an innovative new diagnostic system for analysis of biological and medical samples. Our Biospex Analyser uses a unique laser technology and AI methods that allows to get much faster and more accurate results. With our novel approach, we aim to help health professionals to reach rapid and effective therapy decisions.



Your tasks:

- Definition of project-specific quality and approval requirements
- Regulatory support of the development of IVD devices and IVD software with regard to applicable legal and normative requirements
- Support in the development of strategies for the international approval of devices and software for in vitro diagnostics (IVD) and their implementation
- Preparation and maintenance of technical documentation according to IVDR and international regulations
- Development, implementation, and support of a quality management system according to EN ISO 13485 and other ISO norms relevant for IVDR
- Creation and management of documentation according to EN ISO 13485 and other ISO norms relevant for IVDR
- Compilation of technical documentation for submission to authorities
- Definition of quality requirements and their implementation in all areas of the company and at suppliers
- Conformity assessment according to in vitro diagnostic regulation
- Review and evaluation of approval-relevant product changes
- Support of the company's internal risk management activities

Your profile:

- Successfully completed technical or scientific studies or a comparable qualification
- At least 3 years of experience in the field of medical device approvals with a focus on devices and software (experience in the IVD field is an advantage)
- Experience in clinical evaluation testing
- A good understanding of software products is a plus
- High sense of responsibility as well as a structured and analytical way of working
- Very good command of written and spoken English (at least B2 level)
- Strong communication and coordination skills
- Willingness to participate in training measures and conferences

Our offer:

- Permanent position
- Flexible working hours, flexitime and the opportunity to work remotely
- Modern and bright office space
- Up-to-date office equipment and IT infrastructure
- Free parking spaces and attractive surroundings with shops
- Free drinks & regular team events
- Multinational, highly qualified & professional team
- Flat hierarchies with "open door policy"
- Contribute your ideas and implement them

Did we raise your interest?

Please submit your application documents including your earliest possible starting date and salary expectations to **Petra Deubler** at the following E-mail address: career@microphotonx.com

We look forward to your application.