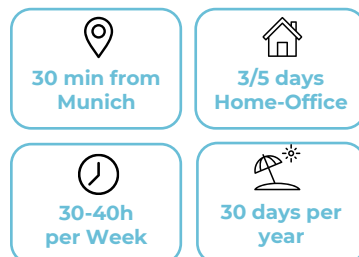


## Regulatory and Quality Manager (m/f/d)

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 acquire fast and accurate results. With our novel approach, we aim to help health professionals to reach rapid and effective therapy decisions.

As of February, our premises will move from Tutzing to Martinsried. If one of these locations is an exclusion criterion for you, please apply anyway - we will be happy to evaluate remote working options in a joint dialog.



### Your tasks:

- Definition of project-specific quality and approval requirements
- Regulatory support of the development of IVD devices and IVD software with regards 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:

- Opportunity to contribute your ideas to an innovative, state of the art solution to medical diagnostics
- Paid internship spanning a period of 6 months
- Flexible working hours and the opportunity to work remotely
- Modern and bright office space
- Free parking spaces
- Attractive surroundings with shops and

### Did we raise your interest?

Please submit your application documents including your earliest possible starting date and salary expectations to the following E-mail address: [career@microphotonx.com](mailto:career@microphotonx.com)

**We look forward to your application.**