

## Quality Manager (m/f/d)

Permanent position, full-time | Vienna / Remote

Are you a passionate Quality Manager with hands-on mentality? Are you excited by overseeing and enhancing the quality process within our company and its medical products for cancer screening and treatment? Are you eager to bring the next generation of CE-IVD marked microbiome diagnostics for doctors onto the market? Then we can't wait to meet you!

This is a one-time unique opportunity if you want to change the diagnostic landscape in Europe!

### What you will be doing

- Maintaining and reviewing electronic QMS according to ISO 13485, ISO 9001 and IVDR
- Coordinating and overseeing risk management activities
- Providing support for planning and supervising clinical trials in compliance with ISO 14155
- Leading our in vitro diagnostics certification process and oversee the continuous compliance for in vitro diagnostics and medical software (MDR, IVDR)
- Ensuring that market surveillance and reporting is carried out in accordance with EU directives
- Analyze and interpret international laws, ordinances and standards for medical device manufacturers and independently derive the resulting regulatory requirements for our product
- Adapting of product information to national regulatory requirements
- Ensuring compliance with SOPs and all relevant regulatory and legal requirements
- Managing the recording, processing, and assessment of deviations - preparation of CAPAs
- Supporting internal audits and inspections by authorities

### Your profile

- Passion for quality management and regulatory affairs
- At least one year of professional experience in quality management or regulatory affairs of medical devices
- Experience with clinical development and regulatory filings as well as with certification of MD/IVD and/or related software solutions
- Demonstration of high level of organization, multi-tasking, judgement, and analytical skills
- Team spirit and interest in medical-technical topics
- Understanding for software, life sciences and machine learning
- Work experience with Atlassian tools such as Confluence and Jira

### What we offer

- An autonomous company culture, where every person can change the future of medical diagnostics!
- Flexible working hours with work-from-home option.
- Good career opportunities in a successful international start-up with attractive personal growth experience.
- Work with an awesome team where you take over responsibilities from day one.
- Numerous company events throughout the year - both on-site and remote!
- Possibility of acquiring shares in the company.
- For this position, the minimum monthly gross salary is EUR 3,500 (full-time), in accordance with the collective agreement. We offer attractive over-payment, depending on your qualification and experience!

### About us

We are a young medical technology team dealing with the micro universe within us - the microbiome. As the world's first ISO certified company in the field of microbiome analysis, we are developing breakthrough analysis tests for cancer prevention and treatment which are used by doctors, patients, hospitals, and white-label partners throughout Europe. Now it is time to launch our first medical diagnostic product, BiomeOne. This biomarker is a predictive test for immunotherapy in cancer. Together we will take medical diagnostics to a new level!

At Biome Diagnostics, you are part of an international team that believes in diversity and the huge potential within it. We welcome and support people of all backgrounds and identities and want to ensure equal opportunities for all.

If you would like to revolutionise medical diagnostics together with us, then send an application to Nikolaus Gasche by e-mail: [office@biome-dx.com](mailto:office@biome-dx.com)