

To strengthen our Quality Team in Berlin, we are looking for a

Quality Assurance Specialist (m/w/d)

Tasks and Responsibilities:

- Maintenance and continued development of the quality system compliant with FDA's Quality System Regulation (21 CFR Part 820) and ISO 13485
- Assist cross-functional partners (e.g. development, manufacturing, commercial, etc.) in quality assurance activities including projects and day-to-day operations
- Support administration of the document control and training programs, assign document numbers, route procedures for review and approval, and track/organize employee training records
- Support product acceptance activities per internal standard operating procedures and policies
- Maintain and monitor quality record logs for equipment, deviations, CAPA, complaints, audits, etc. Provide maintenance support to these systems as directed by supervisor
- Assist in identifying, analyzing, and interpreting quality metrics to measure the effectiveness of the quality system
- Prepare agendas and capture meeting minutes for designated quality system meetings
Organize and track action items as required
- Support quality management in supplier, internal, and external audits as needed
- Provide suggestions for continuous improvement of company products and processes

Minimal Skills & Qualifications:

- Academic degree or equivalent work-related experience in a science related field
- 1-2 years previous experience in a quality function, or related work experience in collaborating with a quality team, or quality assurance related academic experience
- Experience in an industry regulated by FDA, or knowledge of the ISO 13485 Standard preferred. Experience with In Vitro Diagnostics (IVDs) a plus
- Ability to manage and prioritize multiple daily and weekly tasks as directed by supervisor
- Strong organizational skills
- Excellent communication skills, professional and confident when dealing with internal partners
- Team spirit and pragmatic, goal-oriented working style
- "Hand's on" mentality with and absolute willingness to work in a fast-paced environment
- Demonstrated ability to learn new information quickly
- Fluent in German and English

Are you reliable, flexible and like working in a team? Then we would like to get to know you.

We offer:

- A forward-looking company with a corporate culture based on flat hierarchies, openness and fairness
- A modern and international working environment
- Space for independent work
- Personal development through training programs
- Flexible working times models and performance-based compensation

Further information regarding this position can be obtained from Joel Centeno, Senior Vice President Regulatory & Quality

Email: joel.centeno@epigenomics.com

If interested, please email your complete application with salary expectations and possible start date to:

careers@epigenomics.com