

Director Quality Management Systems (m/f/n)

Freelance-ID: OCR-FL-2897

The Director Quality Management Systems is responsible for developing, implementing and maintaining all applicable systems and processes that ensure the quality, reliability, and regulatory compliance of products and services in the field of API production and In-Vitro-Diagnostics. This applies to all regional activities as well as supporting all activities of the global quality management system.

Tasks:

- Develop, implement and maintain systems to meet all applicable external standards relating to the company activities and products. These standards include, ISO 9001, ISO 13485, ISO 14971, IVDD / IVDR, FDA QSR
- Develop and maintain systems to measure performance against applicable quality and regulatory standards, and take necessary action to communicate, advise, and/or assist according to performance levels
- Establish and implement communication strategy for the improvement and awareness of quality and regulatory issues across all departments
- Plan and manage activities in accordance with agreed budgets and schedules
- Participate in, and contribute to, the divisional quality management teams in other sites
- Closely work together with all other relevant departments; Indirect supervision of all quality relevant activities

Skills:

- Bachelor's degree in engineering or a specific scientific field, or demonstrably equivalent training and experience
- Demonstrated multi-year work experience in managing a quality team
- In-depth knowledge of ISO 9001, ISO 13485, ISO 14971, IVDD / IVDR, FDA QSR (also managing FDA inspections)
- Computer Skills: Office, SAP and quality specific tools (e.g. GAS, Master Control, MiniTab) to achieve the objectives
- Certificates, Licenses, Registrations: Lead auditor training, FDA QSR, PRRC trainings, etc. is a plus
- Fluent in German and English
- Some background in statistics is essential

Additional Information:

Location: Berlin and other
Start: Asap, latest January 2025
Duration: 6 months
Capacity: 4-5 days/week
Remote share: tbd.

Your OCR contact

Roman Sperling
phone: 07472-95176-22
mobile: 017656947363
Email: rs@oc-recruitment.de