Profil is an internationally renowned CRO in the field of metabolic diseases, founded in 1999.

For many years, we have been working closely with the pharmaceutical industry to develop new drugs for the treatment of diabetes and related diseases. We also intensively support the further development of known active substances. Furthermore, we conduct vital research regarding various other exciting applications such as novel routes of insulin administration or the measurement of blood glucose concentrations. Our many years of experience have enabled us to build up comprehensive scientific know-how and a unique expertise in the field of metabolic diseases. Profil currently employs around 380 people who make an important contribution to improving the quality of life of people with diabetes.

We are looking for a

Senior Quality Assurance (QA) Manager (m/w/d) Clinical Trials

*We are seeking an experienced and motivated **Senior Quality Assurance (QA) Manager – Clinical Trials** to further develop our QA function within the clinical research environment. This role combines hands-on quality expertise with close collaboration with cross-functional and international stakeholders.*

Key Responsibilities:

- Plan, conduct, report and track **internal and external audits** (e.g. process audits, vendor qualification audits, system and study specific audits and inspections)
- Ensure compliance with GCP, ICH guidelines, FDA regulations, applicable regulatory requirements, and company standards
- Own and manage **Deviation and CAPA processes**, including root cause analysis, tracking, and effectiveness checks
- Drive **risk management activities**, including risk assessments and mitigation strategies
- Lead and support **change management processes** related to quality systems and clinical operations
- Responsible for the creation, review, approval, and lifecycle management of QA SOPs
- Preparation of role-based training materials and conduct of training courses in the GCP/FDA regulated setting
- Prepare quality metrics, management reports, and audit summaries for upper management

- Act as a key QA contact for regulatory inspections and sponsor audits
- Collaborate closely with Clinical Operations, Project Management, Regulatory Affairs, Data Management, Medical Writing and external partners
- Support continuous improvement initiatives within the Quality Management System (QMS)
- Review and approve **validation documentation** (e.g. validation plans, risk assessments, test scripts, validation reports) for computerized systems, including eQMS and other GxP-relevant systems

Qualifications & Experiences:

- University degree in Life Sciences, Pharmacy, Medicine, or a related field
- **Several years of professional experience in Quality Assurance** within clinical trials
- Senior QA professional
- Strong knowledge of **GCP, ICH and international regulatory requirements (e.g. FDA regulations)**
- Demonstrated experience in:
    - Audit planning, performance, and reporting
    - Deviation and CAPA management
    - Risk management
    - Change management
    - SOP and training management
- **Fluent in German and English**, both written and spoken
- **Willingness to travel** nationally and internationally, particularly within/to **Germany, within Europe and the USA**
- Strong organizational, analytical, and problem-solving skills
- Confident communication style and ability to work with stakeholders at all levels

What we offer:

- A responsible senior role in an international clinical research environment
- High level of autonomy and the opportunity to actively shape QA processes
- Collaboration with global teams and exposure to international projects
- A thorough and practice-oriented onboarding
- Performance-based compensation and flexible working hours
- A company culture strongly characterized by trust and collegiality
- An exciting workplace with opportunities for professional and personal development, for example development into a team lead function

Are you interested in this role? Don’t hesitate to send us your CV, a motivation letter as well as records of your qualifications/ employment reference letters via email, preferrably as pdfs, to: hr@profil.com

Profil Institut für Stoffwechselforschung GmbH

Christina Seeck
Team Lead Human Resources
Hellersbergstraße 9
41460 Neuss

www.profil.com

JETZT BEWERBEN