About Wemedoo

Wemedoo is a leader in clinical informatics, offering a comprehensive SaaS solution and accompanying professional services for the clinical research industry. Our SaaS solution, oomnia, integrates multiple essential functions for clinical trial management, including EDC, RTMS, ePRO/eCOA, eTMF, eConsent, and CTMS all in a single unified software. Our award-winning professional services include medical writing, data management, eTMF management, and biostatistics. We help a diverse range of clients, including CROs, sponsors, government bodies, NGOs, and academic institutions, enabling them to achieve efficient, high-quality clinical research outcomes.

Position: Quality Manager

Location: Zug

Employment Type: Full-Time

Key Responsibilities:

- Lead the development, implementation, and continuous improvement of the Quality Management System (QMS) in compliance with ISO 13485, ISO 9001, MDR, and GCP standards.
- Oversee the creation, updating, and management of QMS documentation, ensuring all processes align with the latest regulatory requirements.
- Drive internal audits and prepare for external ISO certification audits, ensuring the company meets all necessary compliance standards.
- Implement and manage quality processes, including CAPA, risk management, and corrective actions, to ensure adherence to ISO 13485 and related standards.
- Provide training and guidance to staff on ISO requirements and quality best practices, ensuring a company-wide commitment to compliance and quality.
- Maintain and enhance quality data collection and reporting systems, driving continuous improvement across all functions.
- Foster and maintain effective working relationships with internal teams and external regulatory bodies to support quality objectives.

Requirements:

- University degree in a scientific field, preferably in chemistry.
- Extensive knowledge and hands-on experience with ISO 13485, ISO 9001, MDR, and GCP.
- Several years of quality management experience, ideally within a laboratory environment.
- Mandatory certification in Quality Management.
- Proficiency in quality management tools and methodologies, including FMEA, 8D Report, Cause and Effect Diagram, and 5 Why Method.

- Proven experience in training and mentoring staff on ISO standards and practices.
- Mandatory certification as an Internal Auditor for ISO standards.
- Strong attention to detail with excellent organizational skills.
- Exceptional analytical and problem-solving abilities.
- Fluent in both English and German

What We Offer:

- A dynamic and innovative work environment.
- Opportunities to work with leading-edge technology in clinical research.
- Professional development and growth within a fast-growing company.
- Competitive salary, commission structure, and benefits package.

How to Apply:

If you are ready to join a forward-thinking team and help drive the growth of oomnia in the clinical research industry, we want to hear from you. Please send your CV and a motivation letter outlining your experience and suitability for this position to admin@wemedoo.com. Only candidates who submit a motivation letter will be considered.

Deadline for Applications: 31 October 2024