

Quality Manager (m/f/d)

ASTRUM is a leading Clinical Research Organization (CRO) providing innovative solutions for clinical trials. Our international team of experts supports pharmaceutical and biotech companies with a focus on quality, efficiency, and patient-centered solutions. ASTRUM Quality & Compliance (Q&C) have an exciting opportunity for an experienced Quality Manager to join their recently restructured, small, highly motivated and enthusiastic global team.

The ideal candidate will enjoy solving problems, be process focused, able to use metrics to understand performance and proactively drive changes that will enable continuous improvement.

Responsibilities include:

- Develop quality standards, processes and procedures, and reviewing existing processes to assess compliance with regulatory requirements and support continuous improvement.
- Monitor and manage quality issues throughout the clinical development process to proactively provide quality data to support improved business decisions.
- Coordinate cross-functional teams to investigate quality issues, conduct Root Cause Analyses (RCA) and identify areas for improvement
- Collaborate with cross-functional teams to develop and implement Corrective and Preventive Actions (CAPA) to resolve quality-related issues
- Create reports and documentation related to quality issues, proactively identify risk areas and provide regular quality performance metrics to Global Head of Q&C
- Prepare for and support internal and external audits, including inspections by regulatory authorities
- Proactive support continuous improvement of the Quality Management System (QMS)
- Act as the central quality contact person for all internal and external quality-related issues
- Creation of quality policy goals in cooperation with the Global Head of Q&C

Requirements:

- A degree in a relevant field (e.g., pharmacy, biology, medicine, engineering) or equivalent qualification
- 2-5 years of experience in quality management, ideally in clinical research or a CRO



- In-depth knowledge of regulatory requirements (GCP, ICH) and experience managing quality issues
- Strong analytical skills with the ability to perform Root Cause Analyses
- Excellent communication skills and the ability to work effectively in cross-functional teams
- Proficiency in English, spoken and written
- Self-motivated, structured, and solution-oriented approach with a strong ability to work in a team

What we offer:

- A challenging position within a dynamic and growing company
- Opportunities for personal development and training
- An international work environment with exciting projects and renowned clients
- The option for remote work
- Competitive salary

Do you want to join our team? We look forward to receiving your application! Please send your complete application (cover letter, CV, certificates) including your salary expectations and earliest possible start date via email to:

Stephanie.May@astrumcro.com