Associate Director/Director, Quality Assurance and Compliance

Position Summary:

This individual will be a hands-on, individual contributor within Quality Assurance and Compliance (QAC). This role helps to bridge operational quality assurance with regulatory compliance by partnering externally and internally with Clinical Development Operations, Clinical Operations, CMC/ Clinical Supply Management, and Regulatory Affairs, and other stakeholders to ensure our studies are conducted to the highest standards of data integrity, patient safety, and regulatory compliance. This position reports to the Senior Director, Quality Assurance and Compliance.

Duties and Responsibilities:

- Serve as the clinical QA lead for assigned clinical studies, providing GCP guidance to study teams, CROs, and investigator sites throughout study conduct.
- Develop, implement, and maintain a risk-based clinical quality management system (QMS), including SOPs, quality plans, and quality risk management processes aligned with ICH E6 (R3) and applicable regulations.
- Manage the CAPA system for clinical quality issues, ensuring timely investigation and resolution.
- Plan and execute GCP audit programs, including CRO, vendor, investigator site, TMF, and system/process audits; author audit reports and drive corrective and preventive action (CAPA) plans to closure.
- Lead inspection readiness activities and serve as a key point of contact during health authority inspections, including mock inspections and front/ back-room support.
- Review critical clinical trial documents (protocols, amendments, and other essential records) from a quality and compliance perspective.
- Oversee TMF quality oversight, ensuring inspection-readiness and completeness in partnership with Clinical Operations.
- Support vendor and CRO qualification, oversight, and governance from a quality standpoint, including quality agreements.
- Contribute to and continuously improve GCP training programs across the organization.
- Ensure training records are current and audit-ready; partner with document control to align training assignments with SOP updates.
- Travel may be required, as necessary.
- Additional duties and ad hoc projects, as required

Qualifications:

Education and Experience:

- Bachelor's degree or higher in a Science, Medical, or related discipline required.
- 7+ years of experience (Associate Director) or 10+ years of experience (Director) in pharmaceutical, biotechnology, or healthcare industry with drug development experience.

- Minimum of 5 years working in Quality, Compliance, Clinical Development Quality, or related functions.
- Advanced working knowledge of GCP, ICH guidelines, and FDA/EMA regulations.
- Prior experience in a late-stage (Phase 2b/3 or NDA/BLA-stage) program strongly preferred.
- Demonstrated experience leading quality oversight, inspection readiness, audit programs, and compliance initiatives.
- Experience supporting or leading regulatory inspections.
- Experience with electronic TMF systems and eQMS platforms is required.
- Familiarity with CTMS, EDC, and other clinical systems.
- Strong investigation and root cause analysis experience related to quality events and compliance issues.
- Experience with training program development and administration is a plus.
- Familiarity with document control systems and SOP lifecycle management.

Competencies:

- Able to read, comprehend, write, and speak English fluently.
- Must have excellent written and verbal communication and interpersonal, negotiation, and conflict resolution skills. Able to communicate and present complex information clearly and succinctly, both in writing and orally effectively with cross-functional teams and external partners across all levels.
- Must be analytical with strong problem-solving skills with excellent attention to details and follow-through.
- Proven ability to influence and partner effectively with senior leaders and cross-functional stakeholders
- Comfortable operating as an independent contributor in a lean, fast-moving environment.
- Must be self-motivated, take initiative, and able to work independently with minimal supervision.
- Must be flexible and able to multi-task, prioritize, and meet deadlines in a fast-paced environment.
- Proficient in Microsoft Office Applications (Word, Excel, PowerPoint). Familiar with OneDrive, SharePoint, MS Teams and Zoom a plus.
- Ability to travel up to 15-20% based on business needs.

Physical and Visual Requirements:

While performing the duties of this job, the individual is regularly required to use computers and office equipment, set up computer systems, work with cables and peripherals, troubleshoot equipment, and manipulate documents. This individual will primarily work on-site but must be able to work from home as needed. The individual must be able to travel up 15-20%. The individual will experience prolonged periods of sitting and will also be required to talk or hear, reach with hands and arms, walk, bend, and stand frequently and may occasionally lift or move equipment up to 30 pounds. The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

Note:

This job description in no way states or implies that these are the only duties to be performed by the employee(s) incumbent in this position. Trevi reserves the right to modify, change or add to the position's job duties and responsibilities as business needs may require. This document does not create an employment contract, implied or otherwise, other than an "at will" relationship.

Trevi Therapeutics, Inc. is an Equal Opportunity/Affirmative Action employer including protected Veterans and individuals with disabilities. Trevi considers applicants for employment without regard to, and does not discriminate on the basis of, an individual's sex, race, color, religion, age, disability, status as a veteran, or national or ethnic origin; nor does Trevi discriminate on the basis of sexual orientation or gender identity or expression.