Head of Quality Assurance and Compliance

Position Summary:

The Head of Quality Assurance and Compliance (QAC) is the functional lead for Trevi's quality assurance and compliance efforts, providing management and oversight for all aspects of QAC for the company. This role is primarily responsible for ensuring that Trevi's clinical studies and product development meet all regulatory quality standards and internal policies. The ideal candidate will have a strong background in the pharmaceutical industry and expertise in compliance with Good Clinical Practice (GCP) and Good Manufacturing Practice (GMP). Responsibilities include partnering with internal and external cross-functional stakeholders on quality related activities, providing expertise to manage internal and external audits, computer system validation programs and related continuous improvement opportunities, and ensuring that the Trevi Quality Management System is maintained in a state of audit readiness that supports the clinical research activities performed at Trevi.

Duties and Responsibilities:

- Leads the Company' quality assurance and compliance efforts.
- Oversees the development, implementation, on-going assessment, and maintenance of a robust Quality Management System (QMS) to ensure compliance with regulatory requirements and industry standards (e.g., FDA, EMA, ICH).
- Oversees the QAC program of audits and inspections (qualification, routine, and/or for-cause) of clinical sites, vendors, and internal processes to ensure compliance with GCP and GMP. Travel to clinical or vendor sites may be required.
- Assesses the impact of audit/inspection findings on subject safety, data integrity, and business operations.
- Ensures that any identified compliance risks are escalated to Senior Management and oversees the development and implementation of appropriate corrective and/or preventative action plans to address/mitigate those risks.
- Leads or facilitates the investigation of quality events and/or potential serious breaches and analyzes the findings to identify root cause(s). Liaises with key team members to develop and implement proposed actions, documents and tracks appropriate CAPAs, and coordinates with Regulatory for submission to regulatory authorities, as needed.
- Manages activities for inspections by FDA, other regulatory agencies, and commercial partners.
    - Leads and/or assists with cross-functional inspection readiness and preparedness activities
    - Leads/coordinates activities during a regulatory inspection
    - Coordinates with stakeholders to ensure appropriate responses and follow-up to inspection findings are provided in a timely manner
- Chairs the Quality Council and manages the process to assess the company's quality management systems to ensure they continue to be effective, suitable, and adequate.
- Actively partners with key stakeholders in clinical development activities to ensure appropriate quality standards are met.
- Serves as a resource to cross-functional teams for GCP and GMP.

- Oversees the implementation, maintenance, and management of the standard operating procedure (SOP) system and training programs. Develops, reviews, and/or contributes to the development of SOPs, as appropriate.
- Leads, develops, and mentors direct reports
- Additional duties as assigned

Qualifications:

To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skills, and/or abilities required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

Education and Experience:

- Bachelor's degree required in science, engineering, or another relevant technical field.
- Minimum 15+ years of experience with 10+ in biotech or pharmaceutical QAC leadership roles.
- Demonstrated experience managing a group.
- Strong QAC experience gained by working in a GCP regulated clinical research setting.
- Experience in identifying, developing, and implementing organization-wide compliance initiatives.
- Experience hosting and supporting regulatory authority inspections. Audit experience required.
- Knowledge of and experience with the FDA (including 21 CFR Part 11), EMA, and advanced understanding of GxPs (particularly GLP, GCP, and GMP), ICH guidelines, and applicable regulatory requirements.
- Experience with regulatory filing(s) and pre-approval inspections.
- Prior experience working in a startup/clinical stage biotech or pharmaceutical company is a plus.

Competencies:

- Ability to read, comprehend, write, and speak English fluently
- Excellent written and verbal communication skills
- An in-depth understanding of GMP's, GCP's, ICH guidelines and applicable regulatory requirements
- Advanced knowledge and understanding of the drug development process
- Detail-oriented with excellent organizational and time management skills
- Ability to function in a high paced environment with multiple priorities and deadlines
- High degree of flexibility and ability to adapt to changes in priorities
- Proficiency with the Microsoft Office Suite. Experience with Zoom and SharePoint is a plus.

PHYSICAL AND VISUAL REQUIREMENTS:

While performing the duties of this job, the individual is regularly required to use computers and office equipment, manipulate documents, and work in an office environment. This position allows for a hybrid work schedule. The individual may experience prolonged periods of sitting. The employee may occasionally move materials up to 15 pounds. Will be required to travel to clinical and vendor sites as needed.

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.