Head of Quality Assurance and Compliance

Position Summary:

The Head of Quality Assurance and Compliance (QAC) is primarily responsible for the management and oversight of all aspects of QAC for Trevi. Responsibilities include partnering with internal and external cross-functional stakeholders on quality related activities. This position provides quality, regulatory and technical expertise to manage internal and external audits, computer system validation programs and related continuous improvement opportunities. They are also responsible for driving development and implementation of the global approach to Trevi's Quality Management System. They also lead the Quality Council to ensure the Trevi Quality Management System expectations are met and maintained.

Duties and Responsibilities:

- Leads the QAC organization and sets the overall strategy to support the drug development programs of the Company
- Partners with key stakeholders that are integral to clinical development activities to ensure appropriate quality standards are met
- Serves as a strategic Good Clinical Practices (GCP) resource while providing quality and technical guidance to cross-functional teams
- Assesses the quality management systems for suitability and robustness
- Implements and/or maintains the QAC audit program to support all GxP programs
- Leads or facilitates quality events and/or potential serious breach investigations and analyzes the findings to identify root cause(s). Liaises with key team members to develop and implement proposed actions.
    - Documents and tracks appropriate corrective and/or preventive actions.
    - Coordinates with internal and external stakeholders to file with regulatory authorities, as needed
- Ensures qualifications, routine and/or for-cause audits of external CROs, vendors, investigative sites, laboratories to assess effectiveness of their Quality Management System and compliance with approved procedures are scheduled and completed
- Oversees Data Privacy requirements
- Manages and/or conducts domestic and/or international quality audits, while fostering a culture of quality and process improvement
- Assesses impact of audit findings on subject safety, data integrity and business operations
- Ensures that investigative site, vendor, etc., audits are conducted, and identified critical compliance risks are mitigated and escalated to Senior Management, with the appropriate corrective and/or preventive action plans developed and implemented
- Develops and/or reviews, or contribute to the development of standard operating procedural (SOPs) documents
- Coordinates and/or leads risk assessment activities
- Leads and/or assists with cross-functional inspection readiness and preparedness activities
    - Leads regulatory inspection activities
    - Coordinates with stakeholders to ensure timely and appropriate responses and follow-up to inspection findings

- Lead, develop and mentor 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 other relevant technical field.
- Minimum 15+ years of experience with 10+ in QAC leadership roles.
- Demonstrated ability to manage a department.
- Strong QAC experience gained by working in a clinical research setting.
- In-depth knowledge and understanding of local and global industry standards and regulations related to quality control.
- Ability to translate and articulate appropriate strategies and activities to ensure compliance with regulations relative to quality management systems.
- Experience working with complex organizations, working closely with colleagues.
- Experience in identifying, developing, and implementing organization-wide compliance initiatives.
- Experience hosting and supporting regulatory authority inspections. Audit experience required.
- Ability to influence and work effectively with various stakeholders, regions and cultures.
- Advance knowledge and understanding of the drug development process, scientific methods and thought processes, specifically the manufacturing process, to ensure regulatory information is current
- Knowledge and experience with the following:
    - FDA, EMA,
    - 21 CFR Part 11
    - GxPs (Good Clinical Practices, Good Laboratory Practices, Good Pharmacovigilance Practices, Good Data and Documentation Practices, Good Manufacturing Practices and Good Distribution Practices).
- An in-depth understanding of cGMP and ICH Quality guidelines is required.
- Experience with complex regulatory filing(s) and post-approval regulatory activities. Prior experience working in a startup/clinical stage biotech or pharmaceutical company is a plus.
- Result-driven with ideas to drive continuous improvement process simplification with breakthrough solutions, including digital.
- Demonstrated strong cross-functional leadership skills.

Competencies:

- Ability to read, comprehend, write, and speak English fluently.
- Excellent written and verbal communication and interpersonal, negotiation, judgement and conflict resolution skills. Able to communicate complex information clearly and succinctly, verbally and written.
- Ability to build relationships and work collaboratively with all levels of individuals across the organization and externally.
- Demonstrated ability to lead teams in complex environments.

- Detail-oriented with excellent organizational and time management skills.
- Ability to function in a high pace environment, multi-task, manage and prioritize various and differing projects, as well as work effectively toward numerous deadlines.
- Demonstrated analytical capabilities with the ability to analyze a wide variety of information and data to make management decisions regarding potential risks associated with regulatory compliance, formulate action plans, and implement solutions.
- Demonstrated ability to anticipate potential problems and risks related to quality management systems expectations and regulatory compliance, formulate plans, and implement solutions.
- Demonstrated proficiency in conflict mitigation and resolution.
- High degree of flexibility and ability to adapt to changes in priorities
- Advanced understanding of GMP's, GCP's, ICH guidelines and applicable regulatory requirements is required.
- Demonstrated integrity, professionalism, and confidence.
- Advanced computer skills, including Microsoft Office (Word, PowerPoint, Outlook), Zoom and Internet. Experience with SharePoint is a plus.
- Ability to work independently and in a team environment and contribute to the achievement of program objectives.

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 requires the ability to work a hybrid schedule. The individual may experience prolonged periods of sitting. The employee may occasionally move materials up to 15 pounds. May be required to travel to 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.