Senior Specialist, Quality Assurance & Compliance

Position Summary:

The Quality Assurance & Compliance (QAC) Senior Specialist is responsible for managing Trevi's controlled documents, workflows and quality system records in Quality Management System (QMS), This role also supports the GxP training program and performs GMP document review to ensure Trevi compliant with applicable regulatory requirements and quality standards such as but not limited to (FDA, cGxP, ICH, etc.) along with Trevi's internal quality policies and procedures. This position reports directly to the Senior Director of QAC.

Duties and Responsibilities:

Document Management

- Manage and maintain controlled documents in electronic Quality Management System (eQMS)
- Coordinate the review and approval of controlled documents within eQMS
- Maintain revision and approval status of all controlled documents
- Ensure the lifecycle of controlled documents is tracked in eQMS

Training

- Support the overall company GxP training program by maintaining training records and managing periodic review and updates of the training curricula
- Ensure new or updated quality procedures are assigned to relevant personnel for training per learning needs related to assigned role and task
- Track and trend training performance, metrics across the organization and generate training reports

Quality Systems

- Manage the quality system records in eQMS including, but not limited to, deviations, quality events, CAPAs and change controls, etc.
- Support the QA assessment/review/approval for deviations, change controls, and Corrective and Preventive Actions (CAPAs)
- Provide support in continuous improvement of the Trevi's QMS, including documentation, traceability, eQMS updates, etc.

GMP Document Review

- Review and approve batch records, analytical testing results, stability data and reports, Certificates of Analysis, release documentation for drug substance and/or drug product, temperature excursion reports and other GMP documents

Additional Responsibilities

- Assist in the Quality Management Review process by generating quality system metrics, status reports, trend reports, and escalating issues as necessary

- Collaborate with cross-functional teams and leaders to support other organizational areas as they relate to quality assurance and compliance
- Support eQMS users with workflow handling as needed
- Assist with Continuous Process Improvement initiatives led by QAC
- Additional duties and ad hoc projects, as required

Qualifications:

Education and Experience:

- Bachelor's degree in Life Science or related field or Bachelor's degree with experience in Life Science or related field
- Minimum of 3 years of relevant experience in Quality Assurance or related role in a biotechnology or pharmaceutical or contracted research organization
- Demonstrated understanding of Quality Management Principles is required
- Minimum of 2 years' experience managing documents and workflows in eQMS
- Prior experience working with Quality Management Systems is required.
- Knowledge and experience in GxP required.
- Experience in regulatory authority inspections or inspection readiness is a plus.

Competencies:

- Excellent written and verbal communication and interpersonal skills with an ability to communicate across all levels
- Ability to collaborate effectively with the cross-functional teams and external partners
- Must be self-motivated, take initiative, and able to work independently with minimal supervision
- Strong organizational skills.
- Excellent attention to details and follow-through are critical
- Must be analytical with strong problem-solving skills
- Proficient in the Microsoft Office Application (Word, Excel, PowerPoint)
- Familiar with OneDrive, SharePoint, MS Teams, Zoom

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 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.