Senior Quality Assurance Associate

POSITION SUMMARY

The Senior Quality Assurance Associate will support the company's quality and regulatory systems in compliance with industry best practices. They will implement and maintain corporate and departmental procedures. This position will additionally serve as an integral member representing quality on cross functional teams and supports all functional areas with needs related to QMS documentation.

ESSENTIAL FUNCTIONS AND RESPONSIBILITIES

- Perform Quality Assurance activities to ensure compliance with internal processes and procedures and applicable US and international regulatory requirements in support of GMP and GCP procedures.
- Review all documentation for release of drug substance and drug product including manufacturing batch records, executed Batch Records, stability protocols and reports, and specifications.
- Management and Tracking of external Vendor Quality Events & CAPAs
- Coordinate the review, approval, issue and maintenance of QA controlled documents and records including SOPs, Templates, and Technical Reports.
- Process internal deviations, investigations, CAPAs, and change controls.
- Assist with the Vendor Qualification Audit Program for GxP contract service providers.
- Support or perform internal and external vendor qualification audits, as needed.
- Support regulatory inspections and inspection readiness activities.
- Other responsibilities and duties as assigned.

JOB QUALIFICATIONS

Education, Certifications, Experience

- Bachelor's Degree or equivalent combination of education and experience.
- 5+ years of experience in a quality document management, quality assurance, or quality systems in pharmaceutical or bio-pharmaceutical field.

Knowledge, Skills and Abilities

- Strong knowledge of GXP, SOPs and quality system processes.
- Experience in managing both internal and external records, quality-controlled documents, revision workflows and document change control processes.
- Good verbal, written, and interpersonal communication skills are required.
- Demonstrates working knowledge of Microsoft Office applications, Adobe, and SharePoint.
- Excellent organizational skills and ability to review processes or procedures.

SPECIAL WORKING CONDITIONS

- Physical Activities: On a continuous basis, sit at desk for a long period of time; intermittently answer telephone and write or use a keyboard to communicate through written means. Some walking and

lifting up to 25 Ibs may be required. The physical demands described representative of those that must be met by an employee to successfully perform the essential functions of this job.

- Willingness and ability to travel for audits of external vendors and suppliers.

Please note this job description is not designed to cover or contain a comprehensive listing of activities, duties or responsibilities that are required of the employee for this job. Duties, responsibilities and activities may change at any time with or without notice.