



Senior Specialist, Quality Assurance

POSITION SUMMARY

The Sr. Specialist, Quality Assurance will support the company's quality and regulatory systems in compliance with industry best practices. They will establish, implement, and maintain quality systems to support corporate and departmental procedures.

ESSENTIAL FUNCTIONS AND RESPONSIBILITIES

These include, but are not limited to:

- Perform Quality Assurance activities to ensure compliance with established company and departmental policies and procedures, objectives, quality systems, and applicable regulations.
- Develop, implement, and support quality systems processes and procedures.
- Perform QA review and approval of Quality System documentation.
- Review executed batch records and documentation and records, and conduct batch disposition of drug substance and drug product.
- Review and approve external Vendor Quality Events, Change Management, and CAPAs.
- Process internal deviations, investigations, CAPAs, and change controls.
- Assist with the Vendor Qualification Audit Program for GxP contract service providers.
- Support internal and external vendor qualification audits, as needed.
- Support regulatory inspections and inspection readiness activities.
- Work collaboratively with Sr. Management and other departmental functions.
- Other responsibilities and duties as assigned.

JOB QUALIFICATIONS

Education, Certifications, Experience

- Bachelor's Degree or equivalent combination of education and experience.
- 7+ years of experience in a quality compliance, quality assurance, or quality systems in pharmaceutical or bio-pharmaceutical field.
- Demonstrated experience with GMP, investigation, and audit processes
- Experience with batch record review and quality system documentation.
- Experience in managing both internal and external records, quality-controlled documents, revision workflows and document change control processes.

Knowledge, Skills and Abilities

- Knowledge of GXP, SOPs, and quality system processes.
- Excellent understanding of regulatory requirements.
- 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.
- Able to take initiative and multitasking.

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 lbs 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.