

JOB DESCRIPTION

Title: Quality Assurance Analyst II
Department: Quality Assurance
Reports to: Quality Assurance Senior Manager
Status: Full-time, Permanent
Location: Building 1503, Delta, BC
Prepared by: John Sun
Prepared date: June 2021

Summary:

Work in a regulated, GMP active pharmaceutical ingredient manufacturing facility, as a key member of the Quality Assurance (QA) team. Provide general quality system supports and provide quality oversight for Engineering GMP activities. Perform QA review of quality documents and records and ensure timely completion of documentation and outstanding quality/compliance issues. Support and promote continuous improvement of Phyton Biotech's quality systems.

Primary Responsibilities (others may be assigned, as required):

- Perform reviews and approvals of Engineering related quality documents and records, including but not limited to the validation documents for facility/utility system, equipment/instrument, and computerized systems
- Review and approve SOPs, deviations, investigations, change controls, protocols, and reports
- Provide quality leadership, training, and support for internal departments, Perform document management activities
- Support and promote continuous improvement of Phyton Biotech's quality systems
- Participate in internal and external audits

Approval authorizations:

- Authorized to approve SOPs, non-conformances, investigations, change controls
- Authorized to approve validation plans, protocols, exceptions, reports and risk assessments

Required Experience, Skills, & Abilities:

- Minimum of 3 years' experience with Quality Assurance validation and CSV in a pharmaceutical environment
- B.Sc. or B.Sc. Eng. in a Life Science related discipline required
- Experience in ISPE GAMP 5, is an asset
- Internal and external auditing experience is preferred
- Proficient in using Microsoft Office
- Excellent attention to detail with strong communication skills in English required
- Collaborative, but comfortable working autonomously with strong interpersonal skills
- Ability to work effectively and successfully in a fast-paced team environment

Competencies Required to Thrive at Phyton Biotech

- Job/Technical Knowledge • Organization/Planning/Priority Management
- Communication & Influence on Others • Self Awareness/Feedback
- Teamwork/Relationships/Customer Focus • Initiative & Drive • Strategic View
- Embodying Phyton Core Values