



JOB DESCRIPTION

Title:	Quality Assurance Analyst II
Department:	Quality Assurance
Reports to:	Quality Assurance Management Team
Status:	Regular, Full-time, Permanent
Location:	Building 1503, Delta, BC
Prepared by:	John Sun
Prepared date:	November 2021

Summary:

Provide quality oversight on API manufacturing activities according to the ICH/FDA/Health Canada GMP guidelines. Support and promote continuous improvement of Phyton Biotech's quality systems.

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

- Reviewing the Master Batch Record, completed manufacturing batch records and forms.
- Review Production SOPs, risk assessments, non-conformances, investigations, change controls, CAPAs, protocols, and reports.
- Release intermediate products, solvents, and raw materials.
- Manage the controlled documents, including printing, distributing, issuing, reconciling, and archiving GMP documents.
- Participate validation activities include equipment, facility/utility system validation, computer system validation, cleaning validation, and process validations.
- Perform internal audits, supports external audits.
- Coordinate with Operations and Sales, lead the product labeling activities.
- Perform data entry of batch information, maintain, and monitor trends.
- Assist with the internal, customer, and regulatory audits/inspections.

Approval Authorizations:

- Authorized to approve Master Batch Records, completed manufacturing batch records, SOPs/forms, risk assessments, non-conformances, investigations, change controls CAPAs, protocols, and reports.
- Authorized to approve release documentation for intermediate products, solvents, and raw materials.

Required Experience, Skills, & Abilities:

- A minimum of 3 years related experience in the pharmaceutical, biopharmaceutical/biotech industry.
- BS in a life-sciences, chemistry/biochemistry, or related discipline required
- Must have critical thinking ability to make quality judgments
- Collaborative, but comfortable working autonomously with strong interpersonal skills
- Solid oral and written communication skills
- Detail-oriented with an eye for quality and accuracy
- Ability to manage tasks independently to meet the quality and timeline requirements
- Must be proficient in using Microsoft Office

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