Phyton Biotech

JOB DESCRIPTION

Title:	Quality Assurance Analyst II – QC Focus
Department:	Quality Assurance
Reports to:	Quality Assurance Director/Quality Assurance Manager
Status:	Regular, Full-time, Permanent
Location:	Building 1503, Delta, BC
Prepared by:	August 2022
Prepared date:	K. Chui

Summary:
Quality Assurance representatives are responsible to support the manufacture of Phyton Biotech's active pharmaceutical ingredients (APIs) and intermediates at development and commercial scale which meet GMP and Phyton Biotech's quality requirements by effectively maintaining the integrity of the production process while supporting customers and regulatory authorities and processes.

Primary Responsibilities (others may be assigned, as required):
Using "proficient level" professional knowledge/experience to:

- Review analytical data for Certificates of Analysis, stability testing, analytical method validations/ transfers, protocols, and reports
- Review SOPs, test methods, non-conformances, OOS, investigations, QC incident reports, CAPAs, change controls, analytical method validation protocols and reports, QC equipment qualification protocols and reports
- Perform document control activities
- Assists with internal, customer and regulatory audits
- Maintain quality system and processes: training, document control, change control, investigation, CAPA, vendor qualification, complaints, recalls

Leadership/Interpersonal Skills/People Management:

- Apply proficient level abilities of following written cGMP procedures and document work performed in a clear legible manner
- Apply proficient level understanding and adherence to cGMP, Phyton's Quality and Safety requirements
- Ability to work with and train and mentor junior department members

Approval Authorizations

Authorized to approve CofAs and release the following:

- Raw material, starting material, and intermediates

Authorized to approve the following documents:

- SOPs, test methods, non-conformances, OOS, investigations, QC incident reports, CAPAs, change controls, analytical method validation protocols and reports, QC equipment qualification protocols and reports

Required Experience, Skills, & Abilities:

- 2 - 5 years work related experience in a pharmaceutical or other life sciences discipline and/or GMP environment
- B.Sc. in chemistry related discipline, or a life-sciences related discipline required
- Experience with chromatography data system, QMS, CSV and ERP systems an asset
- Waters Empower, DeltaV, UniPoint, and SYSPRO experience an asset
- Must be proficient using Microsoft Office
- Detail-oriented with an eye for quality and accuracy
- Collaborative with department members and additional organization colleagues, but comfortable working autonomously with strong interpersonal skills
- Solid oral and written communication skills
- Able to prioritize tasks and multi-task in a fast-faced environment