

## JOB DESCRIPTION

<b>Title:</b>	Senior Manager, Quality Assurance
<b>Department:</b>	Quality Assurance
<b>Reports to:</b>	Quality/Regulatory Affairs Director
<b>Status:</b>	Regular, Full-time, Permanent
<b>Location:</b>	Building 1503, Delta, BC
<b>Prepared by:</b>	T. Cowan
<b>Prepared date:</b>	July 2019

### Summary:

Provides departmental leadership for all QA activities for the company. Establishes and controls operating budget for same. Manage QA personnel and foster the development. Manage and promote continuous improvement of Phyton Biotech's quality systems. Ensures compliance with all internal and governmental GMP and quality requirements.

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

#### Management

- Establish and manage annual departmental G&O's based on corporate G&O's and long-term strategic plan
- Lead and supervise QA personnel
- Hire, train, schedule, and ensure accountability of all direct reports and staff

#### Quality Assurance

- Ensure Phyton's quality system remains compliant with regulatory requirements and industry standards
- Ensure all products and operations are in compliance with any/all internal and governmental GMP, quality, and regulatory requirements
- Lead the formal process of continuous improvement of the quality system and procedures to maximize efficiencies and safety and minimize deviations/incidents/ investigations
- Responsible for batch disposition and approving the release or rejection of batches
- Ensure regulatory and customer inspections are successfully managed and that any related observations are completed in an acceptable and timely manner
- Responsible for performing quality management reviews

#### 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

### **Approval Authorizations**

- Authorized to approve Certificates of Conformance, Certificates of Analysis, deviations, investigations, change controls, SOPs, master batch records, specifications, validation protocols, reports, annual product reviews and agreements
- Authorized to release raw materials, starting materials, intermediates and APIs

### **Required Experience, Skills, & Abilities:**

- A minimum of eight years of experience of increasing responsibility in pharmaceutical quality, or related activities
- BS in an analytical chemistry related discipline, or a life-sciences related discipline required
- A minimum of three years of experience in supervision of employees
- Expert in FDA/EMA/HC GMP's as they relate to API's and pharmaceutical products
- Thorough understanding of the development and commercial drug regulatory requirements
- Strong leadership, priority/project management, written/verbal communication, presentation, and computer skills
- Collaborative, but comfortable working autonomously with strong interpersonal skills
- Detail-oriented with an eye for quality and accuracy
- Solid oral and written communication skills

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