

## JOB DESCRIPTION

<b>Title:</b>	Manufacturing Engineer I (Quality & Validation)
<b>Department:</b>	Engineering and Maintenance
<b>Reports to:</b>	Associate Director, Engineering & Maintenance
<b>Status:</b>	Regular, Full-time, Permanent
<b>Location:</b>	Building 1503, Delta, BC
<b>Prepared By:</b>	R. Cherry
<b>Prepared Date:</b>	September 2021

### Summary:

The Manufacturing Engineer I (Quality & Validation) must be able to follow each project to its conclusion which includes all aspects of specification, installation, commissioning, and qualification including writing technical manuals for maintenance, operation, and training, by working collaboratively with the production department to provide process, qualification, and equipment support.

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

- Ensure that all equipment and facilities comply with all current local, provincial, and federal regulatory and safety guidelines
- Process and follow-up in a timely manner all documentation required by the company, including engineering change controls, engineering work orders, non-conformance, and corrective actions etc.
- Write and execute IQ, OQ and PQ for manufacturing equipment
- Write and execute documentation for Computer System Validation (CSV)
- Perform periodic assessments, risk assessment and/or F.M.E.A. of equipment and systems
- Assist with the on-going analysis of systems and equipment to identify and close any cGMP gaps
- Support the Engineering group during regulatory authority and/or customer audits
- Successful commissioning and qualification of GMP plant and equipment required by Phyton (or our customers) for API production at our Delta, BC facility
- Support the Engineering group during mechanical breakdown or malfunction to assure production equipment is available and functioning in a timely manner to meet customer service requirements. Willingness to support the Engineering & Maintenance department in all aspects of Facility Maintenance.
- Willingness to work overtime and be flexible with schedule a must, with occasional "On-Call" availability

### 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 (GMP):**

- Authorized to approve equipment qualification, commission protocols and reports
- Authorized to approve process validation, cleaning validation master plans, materials specifications, batch records, SOP's, change controls, non-conformance, and investigations
- Authorized to approve process equipment risk assessments

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

- Minimum 5 years' experience preferably in a cGMP regulated environment such as pharmaceutical
- Bachelor of Science Degree in Chemical Engineering, or related engineering discipline
- Must possess strong abilities with a proven track record in the installation, qualification and validation of systems and equipment supporting pharmaceutical API processes
- Plant commissioning experience is desired
- Strong technical writing and communication skills and excellent organizational skills
- Proficient in Microsoft Office, with strong computer skills
- Ability to work across multi-disciplinary teams and interact with all levels of the organization
- Flexibility and Priority Management Skills: ability to handle multiple projects with multiple priorities; ability to adapt to changing needs of the business
- Ability to function independently, highly motivated self-starter
- Strong problem analysis and problem resolution at both a strategic and a functional level
- Detail- oriented with an eye for quality and accuracy

**Certificates, Licenses and Registrations:**

- B.Sc Engineering (Chemical, Mechanical, Electrical) or equivalent advanced degree.
- Professional Engineer (PE or P.Eng) registration is an asset
- Project management and lean Six Sigma certification is an asset

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