

JOB DESCRIPTION

Title:	Process Engineer
Department:	Maintenance and Engineering
Reports to:	Associate Director, Engineering & Maintenance
Status:	Regular, Full-time, Permanent
Location:	Building 1503, Delta, BC
Prepared by:	R. Cherry
Prepared date:	August 2022

Summary:

The Process Engineer will work collaboratively with the manufacturing, development and the quality departments to provide process, qualification and equipment support. The Process Engineer must be able to follow each application and project to its conclusion which includes all aspects of design, specification, installation, commissioning, and qualification including writing technical manuals for maintenance, operation and training. There is also a hands-on aspect of the position that requires an individual be available for equipment calibration and maintenance of the equipment and facilities in direct support of GMP manufacturing operations.

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

- Ensure through efficient design and maintenance that all equipment and facilities comply with all current local, provincial, and federal regulatory and safety guidelines.
- Successful design, cost estimation, project management, construction, commissioning and qualification of GMP plant and equipment required by Phyton (or our customers) for API production at our Delta, BC facility.
- Process and follow-up in a timely manner all documentation required by the company, including engineering change controls, engineering work orders, non-conformance, corrective actions, SOP's, etc.
- Evaluate chemical process technology and pharmaceutical equipment and collaborate on production specifications
- Provide support in sourcing of innovative equipment or process solutions that will improve efficiency and reduce cost of intermediates and products.
- Investigate and troubleshoot process issues as they arise.
- Author and execute IQ, OQ and PQ on manufacturing equipment.
- Develop and conduct research into new technology to improve plant production and reliability.

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

- Support the Engineering group during mechanical breakdown (process, utility or facility) or malfunction to assure production equipment is available and functioning in a timely manner to meet customer service requirements.
- Willingness to work overtime and be flexible with schedule.

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 3 - 5 years' experience preferably in a GMP or other heavily regulated environment such as pharmaceutical.
- Must possess strong abilities with a proven track record in the design, installation, qualification and validation of systems and equipment supporting GMP processes.
- Hands-on experience in the design, installation, and maintenance of pharmaceutical and/or chemical processing equipment.
- Project management and/or plant commissioning experience are desired.
- Strong technical writing and communication skills and excellent organizational skills.
- Strong computer skills, proficient in Microsoft Office. AutoCad experience an asset.
- Ability to work across multi-disciplinary teams and interact with all levels of the organization.
- Flexibility; 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, Process, etc.) or equivalent advanced degree.
- Professional Engineer (PE or P.Eng) registration is an asset.
- Project management, 5S, Six Sigma and/or Kaizen certification is an asset.

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