Phyton Biotech

JOB DESCRIPTION

Title:	Manufacturing Engineer I (Validation)
Department:	Engineering & Maintenance
Reports to:	Associate Director, Engineering & Maintenance
Status:	Regular, Full Time, Permanent
Prepared by:	R. Cherry
Prepared date:	July 2022

Summary:

The Manufacturing Engineer I (Validation) role is to ensure the equipment and/or systems used at Phyton Biotech are qualified, calibrated and maintained to regulatory requirements and industry standards. The role involves working with user departments to establish specification documents for equipment and/or systems. Validation protocols are developed from the specifications and subsequently executed. This role also involves the installation and commissioning of equipment and/or systems.

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

- Write and/or approve specification documents
- Write and/or approve validation protocols and reports (IQ, OQ, PQ, DQ) for utilities, systems, and equipment, including computerized systems (CSV)
- Maintain the equipment management system to regulatory requirements and industry standards
- Maintain the qualification, calibration and preventive maintenance of equipment, utilities, and the facility
- Develop and maintain Engineering SOPs as required/needed
- Provide engineering support for internal departments

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, risk assessments, change controls, non-conformance, and engineering documents

Required Experience, Skills, & Abilities:

- Minimum 2-3 years of related experience required
- Engineering or Science Degree, or Technical Diploma Certificate required
- Must possess strong abilities with a proven track record in the qualification and validation of systems and equipment supporting GMP regulated processes. Pharmaceutical experience a great asset.
- Experience with Computer System Validation, CRF 21 Part 11, GAMP 5 and other related standards required
- Ability to work across multi-disciplinary teams and interact with all levels of the organization
- Must be able to handle multiple projects with multiple priorities; ability to adapt to changing needs of the business
- Equipment commissioning experience is desired
- Strong technical writing, communication skills, and excellent priority management skills required
- Strong computer skills and must be proficient using Microsoft Office
- Detail-oriented with an eye for quality and accuracy
- Collaborative, but comfortable working autonomously with strong interpersonal skills as a highly motivated self-starter
- Solid oral and written communication skills

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**