Phyton Biotech

JOB DESCRIPTION

Title:	Director of Manufacturing
Department:	Manufacturing
Reports to:	General Manager
Status:	Regular, Full-time Permanent
Location:	Building 1527, Delta, BC
Prepared by:	B. Radu
Prepared date:	January 2023

Summary:
The Director or Manufacturing is responsible for the Active Pharmaceutical Ingredient production in a GMP environment. The Director will establish and execute plans to meet production objectives, work effectively with appropriate stakeholders and lead direct reports by assessing and developing skills. The Director will work collaboratively with the other internal groups to continuously improve production processes, bring new products to commercial production, increase efficiency, and reduce cycle time and cost. The Director will provide and present budgetary, staffing and capital recommendations to Senior Management to support Phyton's goals and objectives for manufacturing.

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

- Accomplishes manufacturing results with group by communicating job expectations; planning, monitoring, and appraising job results, coaching, and addressing performance while initiating, coordinating, and applying systems, policies, and procedures
- Maintain and manage the team by selecting, orienting, and training employees while developing personal growth opportunities in a dynamic environment
- Maintain production plan by scheduling, monitoring the processes, personnel, and resources, studying and implementing methods for improvement, developing reporting procedures and systems, facilitating corrections to malfunctions within the process while initiating and fostering a spirit of cooperation within and between departments
- Assist with the development of relationships with potential stakeholders and the entering of contractual relationships with other businesses to produce their products within our facilities.
- Prepare yearly production plan based on sales forecast and update the production plan to meet shifts in demand for both our Canadian facility and China based CMO supplier
- Ensure the operation of equipment by collaborating with support groups for maintenance, commissioning, qualification and equipment upgrade evaluation
- Provide manufacturing information by analyzing and compiling production performance records and data for incorporation into the monthly production report
- Create and revise procedures by analyzing operating practices, forms of control and personnel requirements and effectively implementing changes
- Review equipment qualification, commissioning protocols and reports

- Prepare process validation protocols and validation reports. Review process validation, cleaning validation master plans, materials specifications, batch records, SOP's, change controls, non-conformance, and investigations
- Prepare and revise annual cleaning assessment. Review and assess cleaning validations performed in the previous year and cleaning validations planned for the coming year.
- Prepare and review process equipment risk assessments
- Ensure the production areas are safe and clean by educating and directing personnel on the use of equipment, and resources while maintaining compliance within established policies and procedures
- Provide detailed input with regards to generating the yearly operations budget for materials, equipment and training and updating as required to reflect operational changes
- Act as the Operations representative during regulatory and customer audits
- Attend monthly cross site meeting between Canada and Germany to provide updates of production processes of the Canadian facility
- Coordination, assignment, writing and review of quality related GMP documentation including deviations, investigations, SOP's, protocols, and reports
- Coordinate with Development Service Department to provide technical and equipment set up support, manage the resource, discuss process issues, and respond customer request to ensure that final product meets customer specifications

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 of 7-10 years of successful manufacturing and technical experience with a minimum of 5 years or management experience in pharmaceuticals or other highly regulated environment
- Process or Chemical Engineering or a Master's in Chemistry with extensive process experience with a track record of successful production management
- Knowledge of industrial chemistry reactions and purification
- Ability to effectively lead and motivate a team of technically trained people
- Ability to set and manage guidelines for safety, procedures, and quality
- Excellent leadership, oral, critical thinking, written and communication skills
- Knowledge of business, finance and management principles related to the manufacture of pharmaceutical goods
- Detail-oriented with an eye for quality and accuracy