Production Manager

Department: Operations	FLSA Status: Exempt
Reports to: Director	Location: 110 Terry Drive

BASIC FUNCTION: Responsible for managing the manufacturing of solid dosage forms of tablets and capsules. Production Manager ensures that the Standard Operating Procedure's guidelines and company policies are readily available and met by the Production Supervisor and operators. Ensure the production operators are in compliance with the cGMP requirements.

JOB RESPONSIBILITIES:

- Manage and coordinate with Quality Assurance and Quality Control on all Production activities.
- Production Manager ensures that the Standard Operating Procedure's guidelines and company policies are readily available and met by the Production Supervisor and operators.
- Ensure the production operators are in compliance with the cGMP requirements.
- Maintain required documentation as per cGMP guidelines of the FDA.
- Responsible for all operation employees' training.
- Coordinating all shift schedules.
- Plan, coordinate, troubleshoot and procure all the tools necessary and support the production operators in achieving the productivity targets.
- Ensures that the team leaders are adhering to all safety procedures and identifying/communicating the necessary adjustments to address potential safety concerns. The Manager will also ensure the Supervisor/ team leaders are enforcing the proper wearing of PPE (personal protective equipment).
- Identifies employee development needs based upon personal assessment and feedback from Supervisor/ team leaders.
- Supports and develops a comprehensive continuous and structured training program for the site.
- Works with production teams to ensure that goals are being met.
- Maintains primary communication of performed goals and requirements as identified by production management.
- Focuses on driving productivity improvements while maintaining high quality standards.
- Initiates/supports revision and approval of Batch Manufacturing Records and SOP's.
- Supports attainment of Supervisor/team leaders' goals.
- Works collectively with production, customer service and other necessary areas to ensure timelines are met and results are achieved.
- Writes deviations/investigations and performs root cause analysis to formulate an effective CAPA plan.
- Other duties as assigned.

ESSENTIAL JOB REQUIREMENTS AND QUALIFICATIONS:

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- Bachelor Degree required
- 10 + years of experience in Pharmaceutical industry
- Some understanding of IQ, OQ, and PQ
- Handle and complete special projects as required
- Other duties as required or delegated
- Document all performed analysis as per cGMP, USFDA and 21CFR211.194 guidelines.
- Follow cGMP (current Good Manufacturing Practices), GLP (Good Laboratory Practices), 21CFR211.22, 21CFR211.28 and 21CFR211.170.
- Follow the OSHA (Occupational Safety and Health Administration) and EPA (Environmental Protection Agency) safety regulations.
- Follow all DEA (Drug Enforcement Agency) guidelines
- Computer literate with basic knowledge of Microsoft Office
- Basic knowledge of an Inventory reporting system, e.g., SYSPRO, JDE, SAP, Vantage
- Must have good communication skills
- Must be able to read, write, and communicate in English as well
- Must have leadership skills
- Accuracy reporting to SYSPRO
- Accuracy reporting to batch records
- Entering information in log books for DEA, and FDA purposes
- Must be a critical thinker with a "can do" attitude, and be able to think "outside the box".
- Process troubleshooting

PHYSICAL DEMANDS: While performing the duties of this job, the employee is required to walk, sit, and use hands to finger, handle or feel tools or controls, reach with hands and arms, balance, stoop, crouch, bend, talk and hear. The employee must lift and/or move up to 20 pounds. Specific vision abilities required by the job include close vision, distance vision, color vision, peripheral vision, and depth perception.

The job demands here are representative of those that must be met by an employee to successfully perform the functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions. This job description is not intended and should not be an exhaustive list of all principal job elements essential for recruitment and selection, for making fair job evaluations and for establishing performance standards. The percentage of time spent performing the various job duties is not absolute. The incumbent, who has the right to amend, modify, or terminate this job in part or in whole. This document is not a contract for employment.