Job Title: Production Manager
Departments: Operations
Grade: 12/13 (DOE)
Reports To: Plant Production Manager
Positions Supervised: Manufacturing
Date: April 2021

Purpose:
Provide day-to-day leadership and direction for production teams in the manufacturing department to ensure excellence in execution and product quality. Appropriately manage and allocate production personnel and resources to meet the production schedules. Champion an environment of safety, innovation, lean continuous improvement and adherence to GMPs and GDPs. Leverage an understanding of each process to leverage reports and drive change where possible.

Key Results Areas:

A. As the leader of the Manufacturing production teams, you oversee the day-to-day operations to ensure the pharmaceutical products produced at Tapemark meet both internal and pharmaceutical quality standards. This includes but is not limited to:
   a. Developing and executing on production schedules that meet customer (internal and external) timelines and expectations. This includes understanding all Tapemark manufacturing processes and critical product attributes.
   b. Ensure manufacturing processes and resources are utilized in a reliable, effective, and efficient manner.
   c. Managing production staffing levels and coordinate, with production planner and Plant Production Manager, the allocation of personnel and resources.
      i. Supervision of manufacturing staff across two shifts
      ii. Strong collaboration with Quality, Engineering, R&D, and Project Management
      iii. Work collaboratively to drive to 100% training compliance,
   d. Hands-on leadership in non-conformance and CAPA investigations related to production.
      i. Properly utilize root cause analysis tools
      ii. Ability to write clearly and concisely.
      iii. Work collaboratively to mee NCR/CAPA timelines.
   e. Hands-on leadership in a culture of accountability and adherence to current Good Manufacturing Practices (cGMPs) and Good Documentation Practices (GDP). This includes comprehensive and complete review of executed batch records, forms, and logbooks.
   f. Ensure manufacturing production is in compliance with FDA regulations and internal Standard Operating Procedures (SOPs). Revise/Draft SOPs and work instructions as needed.
   g. Understand and apply TM policies and procedures fairly and consistently.
   h. Ensures safety is a priority for all employees.

B. Act as manufacturing liaison with current and prospective customers. Provide expertise in production analysis, problem solving, and root cause analysis.
   a. Ensures schedules, project status, and plans are provided as necessary.

b. Leads production investigations to find root cause and implement corrective actions.
c. Leads efforts addressing internal and external audit findings related to production.

C. Responsible for assuring appropriate Risk Management activities are performed in accordance with ISO 13485:2016 and TM Quality Management System requirements.

D. Prepares the necessary administrative responsibilities to meet established guidelines.
   a. Reviews and approves time sheets and ensures transmittal of information to Payroll in a timely manner to ensure payment of personnel and recording of job costs.
   b. Collect, review, and generate the necessary documentation to ensure smooth operations. This includes but is not limited to performance reviews, staffing changes, hires, terminations, budget and/or variance information, etc.

E. Champions Tapemark's core values of Excellence, Responsibility, Integrity, Community, Knowledge, and Attitude to ensure the organization's effectiveness and success.

Job Qualifications

Bachelor's degree (Preferably in Engineering, Operations, or Business) with 2+ year's leadership in cGMP manufacturing setting or Associates degree with 4+ year's leadership in cGMP manufacturing setting. Excellent excel, word, PowerPoint, and functional knowledge of MRP systems.
2+ year's experience in operations/plant management
1+ year's experience in the pharmaceutical, medical device industry

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Employee Signature Date