

Job Title: Production Manager
Departments: Operations
Grade: 15
Reports To: V.P. Operations
Positions Supervised: Production Shift Supervisors, Production Planner
Date: January 2020

Purpose:

Provide leadership and direction for production teams ensuring excellence in execution. Appropriately manage and allocate production personnel and resources to meet the production schedule. Provide leadership to production teams from development through commercialization for existing products and the introduction of new products while operating in a cGMP manufacturing environment. Champion an environment of safety, innovation, lean continuous improvement and adherence to GMPs.

Key Results Areas:

- A. Implement and drive strategies within production area to support company vision and achieve departmental objectives. As the leader of the production team, 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 production plans to meet the production schedule.
 - b. Managing production staffing levels and coordinate, with production planner, the allocation of personnel and resources.
 - i. Supervision of shift supervisors and production planner. Supervision of other production personnel as necessary.
 - ii. Collaboration with Engineering, R&D, and Project Management
 - c. Ensuring all production processes are in compliance with GMPs, federal, state and local regulations.
 - d. Maintaining and improving a production training program.
 - e. Lead continuous improvement initiatives.
 - f. Identifying and incorporating industry “best practices” into Tapemark standard operating procedures.
 - g. Forming and utilizing KPI’s to evaluate operational performance. Determine areas of potential cost reduction, program or quality improvement, or policy change.
 - h. Ensure production is in compliance with FDA drug and device and DEA regulations and ISO standards.
 - i. Facilitate staff meetings to provide information, training, and address issues or concerns.
 - j. Understand and apply TM policies and procedures fairly and consistently.
 - k. Ensures safety is a priority for all employees.
 - l. Lead non-conformance and CAPA investigations related to production.
- 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. Interface with internal and external customers on new and existing projects as needed.
 - c. Utilize statistical approaches to measure production.
 - d. Leads production investigations to find root cause and implement corrective actions.

- e. 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 14971:2007 and TM Quality Management System requirements.
- D. Prepares information and performs 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 distribute information and data to appropriate individuals as requested. (Ex: OT, 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 3+ year's leadership in cGMP manufacturing setting or Associates degree with 6+ year's leadership in cGMP manufacturing setting.

5+ year's experience in operations/plant management

3+ year's experience in the pharmaceutical, medical device industry

Knowledge, Skills, and Abilities

Talent Management: Effectively manage the selection, training, and development of staff ensuring workforce stability and excellence for current and future needs.

Performance Management: Evaluating employee performance against established standards, which includes recognizing employee strengths and development needs as well as determining appropriate compensation adjustments. Proactively addressing performance issues when required.

Communication: Effectively communicates, in verbal and written form, with individuals at all levels of the organization. Builds effective relationships at all levels of the organization and inspires trust. Effectively administers and communicates TM's policies and procedures.

Data Driven: Understands statistics and the proper use of data. Demonstrates ability to identify trends, draw conclusions and takes action to achieve results.

Technical: Knowledge of, or ability to obtain knowledge of, equipment and production processes.

Execution: Action and results oriented with a can-do attitude. Implements systems, processes, procedures, specifications and corrective actions that support and deliver results relative to strategic vision.

Influencer: Successfully influences peers, leadership, customers and employees to resolve issues and create alignment toward goals and objectives.

Change Management: Successfully lead people and departments through change initiatives including people, processes, and cultures.

Financial: Managing to a budget and rudimentary understanding of business financials.

Risk Management: Understands and has applied risk management tools, application of current regulations including cGMP, quality processes, procedures and ISO standards – ISO 13485:2016, ISO 9001:2015 to job responsibilities. Develops and implements quality standards, procedures, specifications and corrective actions.