

JOB DESCRIPTION

Position Title: Production Supervisor
Department: Production
Reports To: VP of Manufacturing

POSITION SUMMARY:

Manage a staff of approximately 30 assemblers and activities of production department, applying knowledge of production methods, processes, machines and equipment. Supervises and coordinates activities of workers engaged in assembling, testing, and inspectings. Serves as liason between production and engineering, provide feedback for manufacturability to design and development engineers, and assist product improvement initiatives.

ESSENTIAL FUNCTIONS:

1. Coordinate efforts with other departments including materials, quality, engineering, R&D, and other production departments.
2. Reviews production orders or schedules to ascertain product data, such as types, quantities and specifications of products and scheduled delivery dates in order to plan department operations.
3. Responsible for supervising the day-to-day production, scheduling, staffing, material management, compliance and training activities – to meet customer requirements including deadlines, quality standards and build a safe and effective product
4. Analyzes manufacturing schedule to plan work assignments for group on basis of priority and worker skills; Schedule work for individual employees based on master plan.
5. Examines product according to knowledge of manufacturing and quality standards to insure acceptability; Support quality initiatives and meet quality objectives.
6. Perform/lead technical reviews, investigations and process improvement projects. Provide manufacturing input into integration and validation of new equipment and processes. Resolves technical, material and cGMP problems that may impact product/project deadlines.
7. Provide guidance and help to lead troubleshooting efforts as needed during a deviation in the process. Initiate, own and properly manage work center NCMR's and CAPA's.
8. Hands on, participates in work of subordinates.
9. Supply prototypes and assist in process development for new products
10. Determine short/midrange and long term head count requirements based on budgeted and long term forecasts to ensure adequate resources to meet production schedules.
11. Provides guidance, support, direction and leadership through positive interactions with all personnel during daily operations.
12. Interview, hire, coach, motivate, develop and discipline staff. Conduct annual performance reviews for all direct reports. Assist in setting performance objectives and development plans. Monitor progress. Develop, train and challenge employees for growth and advancement to the next levels.
13. Review, approve, and manage documentation for batch and system records. Assist in release of product for distribution. Assist in meeting product release time goals. Conduct regular reviews of standard procedures and batch record documentation and identify areas for improvement and implement process improvements.
14. Emphasize training programs designed to enable staff to consistently execute all manufacturing processes with strict compliance to cGMPs and safety regulations. Develop

and implement programs to track GMP errors, identify opportunities for improvement and implement activities to reduce errors.

15. Develop and implement work center performance measurement metrics and internal auditing programs in order to routinely evaluate work center performance, operation efficiency and quality. At a minimum, metrics should include Cycle Time, Efficiency, Schedule Adherence, Yields and Absorption. Identify processes to determine efficiencies in both work order closures and headcount. Identify root causes for inefficiency and implement changes as needed based on assessments.
16. Represent the company during FDA inspections, internal and notified body audits. Provide proper training to team members on how to conduct themselves and respond properly during inspections. Provide information as necessary to FDA that establishes credibility and demonstrates compliance with cGMPs.
17. Overtime may be required at times.

EDUCATION, EXPERIENCE AND SKILLS REQUIRED:

1. 3-5 years of manufacturing experience plus 4-6 years supervisory related experience required; In-depth process knowledge of related manufacturing equipment and processes.
2. Good computer skills – Excel, Word & Material Requirements Planning.
3. Medical device & Microscope experience; Experienced understanding of cGMPs and other regulatory guidelines applicable to the medical/pharmaceutical industry.
4. Demonstrated interpersonal and leadership skills; Interfaces well with other departments; Leads effectively and efficiently, supports and fosters a positive, equitable, and safe working environment; Be a champion for Safety.
5. Strong written and verbal English skills. Chinese/Mandarin speaking strongly desired.
6. Previous experience in setting new production lines/facility a plus.
7. Ability to determine (even with limited information) and manage multiple priorities in a manufacturing plant setting
8. Critical thinking, analyzing/interpreting data, and troubleshooting skills.
9. Good communication skills in expressing ideas clearly, responding adequately to detailed inquiries, and comfortable in presenting information to individuals and groups.