



Director of Pharmaceutical Engineering

Job Title:	Director of Pharmaceutical Engineering
Reporting To:	COO

Job Purpose Statement

This position is a key technical role responsible for ensuring consistently high performance of manufacturing equipment and processes. The role requires strong focus on driving quality into production processes, implementation of best practices, and continuous improvement. Additional duties including project management, six sigma methods, and training coordination. This position will require supervision of a technical staff.

Main Accountabilities

- Manage the capital plan maintain projects on time and within budget
- Direct, review and approve change control for product and processes
- Prepare budgets, bids, and contracts, and direct the negotiation of capital projects
- Develop and implement policies, standards and procedures for the engineering and technical work performed in the department
- Have a strong working knowledge of boiler systems, waste water systems and plant chiller/HVAC systems
- Investigate process deviations that occur on manufacturing floor using structured LEAN/SIGMA methods
- Utilize root cause analysis to identify problem source
- Lead and hold accountable a team of Engineers and technical support staff
- Partner with Quality, Operations, and other internal departments to develop quality investigations, assign root cause, and identify/implement CAPA solutions
- Identify and implement cost savings initiatives, specifically facility, quality and efficiency improvements
- Maintain product and company reputation by complying with FDA regulations; and champion manufacturing safety initiatives that align to OSHA standards
- Lead technical improvement projects aimed at zero defects, equipment reliability, and maximized utilization by implementing a highly effective preventive and predictive maintenance program
- Anticipate potential process-related problems, risks, and technical conflicts and develop necessary contingency plans that optimize business continuity
- Ensure work activities are conducted in strict accordance with safety guidelines and processing standards, such as FDA & current Good Manufacturing Practices (cGMPs) and SOPs

- Coordinate and direct projects, making detailed plans to accomplish goals and directing the integration of technical activities
- Analyze technology, resource needs, and market demand, to plan and assess the feasibility of projects
- Plan and direct the installation, testing, operation, maintenance, and repair of facilities and equipment

Education

- Bachelor's degree (or higher) in Chemical Engineering, Mechanical Engineering, Electrical Engineering or a Science-related field
- More than 5 years of experience in a pharmaceutical organization
- Six-Sigma training and project management experience is preferred
- A knowledge of electro-mechanical principles and automated machine process control
- Ability to clearly present technical information and effectively communicate within all levels of the organization
- Demonstrated ability to contribute to and lead project teams
- Clear thinker: simplifying strategy into specific actions with clear accountability, making decisions with speed and accuracy based on best available information and communicating priorities clearly and concisely