Job Description

Manager, Quality Assurance

Job Title: Manager, Quality Assurance
Job Type: Full-time
Job Category: Professional
Department/Division: Quality/Operations
Created Date: 03/21/2018
Revised Date: NA
FLSA Status: Exempt
Shift: Days
Experience: Bachelor's degree with a minimum 4 years of experience in pharmaceutical operations, or a High School Diploma with a minimum of 8 years of experience in pharmaceutical operations, and 2 – 4 years of Supervisory experience required.

Summary

The Manager Quality Assurance will plan, coordinate, and direct the GSMS Quality Assurance program to ensure continuous production of products consistent with U.S. regulatory requirements and GSMS policies and procedures. The Manager Quality Assurance is responsible for Packaging Quality Assurance, Quality Inspection, Quality Receiving and Inspection, and Quality Label/Labelling Operations.

General Duties and Responsibilities:

- Ensures packaging operations and quality assurance activities are performed in adherence to FDA cGMP's.
- Formulates and maintains Quality objectives and coordinates objectives with other operations departments to maximize product quality and reliability and to minimize costs.
- Reports on key quality indicators to upper management.
- Manages and executes the Annual Review process.
- Supervises, directly and indirectly, quality assurance staff. Performs goal setting and performance reviews per GSMS policies.
- Conducts training of personnel as necessary.
- Drives a culture of continuous improvement.
- Develops and ensures adherence to quality-related SOP requirements for receiving, warehouse, and packaging operations.
- Responsible for receiving and inspection of all raw materials, components, and incoming products.
- Approves, issues, and tracks product label and labeling.
- Responsible for packaging room, in-process, and final product approval/release inspections.
- Ensure batch records and related documents are reviewed to ensure quality and compliance.
- Investigates non-conforming events and deviations. Determines product impact. Identifies and implements corrective and preventive actions.
- Dispositions raw materials, components and products. Rejects product that does not conform to required specification.
- Review and approve validation documents (IQ, OQ, PQ, etc.)
- Responsible for GSMS product stability program. Generates and/or approves stability reports as necessary.
- Ensures adequate facility controls are in place, including temperature and humidity monitoring.
- Ensures appropriate warehouse segregation and inventory management.
- Supports change control process for packaging, equipment, facility and procedural changes.

- Responsible for the management of discarded/rejected product waste (controlled & noncontrolled substances).
- Supports regulatory and 3rd party inspections.
- Performs vendor, manufacturer, or internal audits as requested.
- Performs other quality and compliance-related duties as assigned.

Supervision:

Received: Directives from Vice President, Quality
Given: Directives to Quality Assurance Personnel.

Equipment:

Standard office equipment, computers, full-body suit, goggles, cap, booties, gloves, and respirator.

Physical/Cognitive Requirements:

- Quality auditing experience preferred.
- Through knowledge of FDA GMP regulations and quality system regulations/requirements
- Knowledge of manufacturing processes and relevant statistical techniques (Six Sigma, Statistical Process Control).
- Strong communication skills at all levels, both written and verbal; both individually and in a group setting.
- Excellent skills in analytical thinking and problem solving.
- Ability to perform multiple tasks and ability to effectively manage conflict.
- Ability to work in teams to obtain results.
- Proactively identify issues and take action.
- Strong decision-making skills. Ability to make decisions with limited information.
- Effectively manage change and comfortable changing direction and acting without complete information.
- Strong organizational and prioritization skills.
- May be required to work longer than the typical 8-hour work day.
- Primarily sedentary position that requires long periods of desk work.
- Requires light physical duties in keeping work areas clean and organized. Regularly required to walk the production and warehouse areas.

Computer Skills:

- Required working knowledge of basic Microsoft Office applications. More advanced knowledge of data analysis software and reporting (e.g., Excel, etc.).
- Strong internet research skills are required.

Miscellaneous Requirements:

- Maintain a strong attendance record.
- Must be able to pass screening, drug test and background check. Adhere to company's drug-free workplace policies.

Attitude:

- Must be enthusiastic, concerned with job and company as whole, openness with management, and punctual.
- Self-discipline and a desire to achieve results.
- Must be flexible and willing to change.
- Must be detail-oriented.
- Team player, professional, and achieve high quality results.

Acknowledgement

I have received, read, and understood my job description as I serve in the capacity of a Manager, Quality Assurance. I agree to perform the tasks and duties outlined in the job description. Additionally, I understand that the company and I will review these tasks/duties as deemed necessary for updates.

I understand that if I have questions, at any time, regarding the duties and tasks, I will consult with my immediate supervisor or the Human Resources Generalist.

(Please read the Manager, Quality Assurance Job Description carefully to ensure that you understand your responsibilities and expectations before signing this document.)

Regular Employee Signature: _____

Regular Printed Name: _____

Date: _____