QA Supervisor

Department: Quality	FLSA Status: Exempt
Reports to: Manager	Location: 110 Terry Drive

JOB RESPONSIBILITIES:

- Responsible for overseeing and or directing the companies cGMP quality system which has compliance oversight responsibilities of the 5-10 million + solid dosage and encapsulated units produced and packaged daily.
- Assure correct control of label production and issuance, oversee instrument / equipment calibration database
- Assure DEA controlled substances are handled and or reconciled correctly
- Execute and maintain records of SOP and GMP training, final COA disposition and approval signing responsibilities of raw materials and finished goods, batch record auditing / approval, final approval and disposition assignment of new planned deviations, MBR, SOP, process / cleaning IQ, OQ, PQ validation protocols, establishing and assigning product re-test and expiration dates, oversee re-test, receiving, stability, bulk retain and reserve sample database.
- Quality Assurance Personnel Leadership responsibilities included but not limited to: interviewing, hiring, time approval, priority directing, training, and overtime assigning.
- Oversee the direction of QA Inspectors, Lead Investigators, Label Control clerks, MBR document control clerks.
- Continuously audit conditions of all shop floor operations, formulation, blending, compression, encapsulation, coating, polishing, filling, packaging, and labeling.
- Approve or reject all procedures or specifications impacting on the identity, strength, quality, and purity of drug products.
- Annual Product Reviews
- Execute and maintain compliance with 21 CFR 210 and 211
- Sampling of Raw Materials, Packaging and Labeling Components.
- Releasing and Disposition of Raw Materials, Packaging and Labeling Components.
- Issue Batch Records
- Give Line Clearance for weighing, blending, compression, encapsulation, and coating process
- In-Process Testing for Compression: weight, thickness, hardness, and friability
- In-Process Testing for Encapsulation: weight, proper closing of capsule and description
- In Process testing for Coating: weight gain
- Finish product sampling for Quality Control and Quality Assurance
- Calibrations and Maintenance of all machines
- Maintain Stability Schedule.
- Research and gather information in a timely manner
- Prepare, label, organize and maintain files accurately
- Follow all SOPs accurately
- Work with Microsoft Excel, Word, and possibly PowerPoint

- Handle and complete special projects as required
- Have a logical, methodical approach to work, and be precise when taking measurements and recording figures
- Have tact and discretion to point out problems to production workers
- Document all performed analysis as per cGMP, USFDA and 21CFR211.194 guidelines
- Follow cGMP (current Good Manufacturing Practices), 21CFR211.22, 21CFR211.28 and 21CFR211.170.
- Follow the OSHA (Occupational Safety and Health Administration) and EPA (Environmental Protection Agency) safety regulations
- Follow all DEA (Drug Enforcement Agency) guidelines
- Other duties as required or delegated

ESSENTIAL JOB REQUIREMENTS AND QUALIFICATIONS:

- Leadership skills which reflect directives for compliance of all pharmaceutical products
- Innovative
- Naturally positive, upbeat attitude
- Demonstrates a high level of confidence, integrity and motivation
- Knowledge in all aspects of 21 CFR 210 and 211
- Strengths with root cause analysis and technical writing
- Handles confidential and non-routine information with poise, tact, and diplomacy
- Flexible and responsive
- Outstanding organization skills; is detail-oriented self-starter; is able to independently prioritize and multitask; follows through consistently; demonstrates ownership through responsibility and accountability for end product; is proactive and persistent in job efforts; does not get frustrated with time limitations or high pressure situations; works productively when under pressure
- Anticipates and meets the needs of executives, teams and administrative colleagues
- Ability to work effectively in a fast paced, timeline-driven, extremely high-expectation environment; is flexible to occasionally work overtime on short notice
- Takes initiative and exhibits resourcefulness in problem solving; experienced in working in a collaborative team environment
- Maintains confidentiality at all times and exercises solid, dependable judgment and discretion
- Displays effective communication skills, both oral and written (timely, clear, succinct); constructively delivers and receives feedback
- Experience with FMEA and Risk analysis approaches.
- Must understand chemical component and safety practices required for handling chemicals used in batch processing equipment and room cleaning.

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PHYSICAL DEMANDS: While performing the duties of this job, the employee is required to walk, sit, and use hands to finger, handle or feel tools or controls, reach with hands and arms, balance, stoop, crouch, bend, talk and hear. The employee must lift and/or move up to 20 pounds. Specific vision abilities required by the job include close vision, distance vision, color vision, peripheral vision, and depth perception.

The job demands here are representative of those that must be met by an employee to successfully perform the functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions. This job description is not intended and should not be an exhaustive list of all principal job elements essential for recruitment and selection, for making fair job evaluations and for establishing performance standards. The percentage of time spent performing the various job duties is not absolute. The incumbent, who has the right to amend, modify, or terminate this job in part or in whole. This document is not a contract for employment.