Manufacturing Specialist

Full Time
Mt. Laurel, NJ

FLSA Status
Non-exempt

Summary
This position requires an individual who can work within a cGMP environment in collaboration with Operations/Manufacturing Managers and the Production/Procurement Coordinator. The successful candidate must be focused on achieving individual and team productivity goals while maintaining a high level of accuracy.

Essential Duties and Responsibilities include the following. Other duties may be assigned.

- As the steward of detailed manufacturing, learn all manufacturing processes and become the subject matter expert (SME) for all compound pharmacy activities.
- Serve as an SME on current Good Manufacturing Practices (cGMP) and Good Documentation Practices (GDocP).
- Is the primary support in absence of or in assistance for Manufacturing Supervisors as required.
- Once processes are clearly understood, drives improvements to procedures, processes systems and controls.
- Liaison with Quality Assurance Department to facilitate initiation, review, and closure of QMS items (included, but not limited to event, deviation, and CAPA reports, change controls and investigations).
- Act as the manufacturing representative on cross functional projects teams and communicate the relevant information required to successfully execute a manufacturing campaign.
- Originate, revise, approve and/or review GMP documentation including but not limited to:
    - Batch Records
    - SOP's
    - Change Controls
    - Planned Deviations
    - Work Orders
    - Training Programs and Documentation
- Assist in project specific compliance investigations.
- Attend weekly batch meetings.
- Work in collaboration with members of the manufacturing team and other departments such as quality, maintenance, and the laboratory.
- Ability to troubleshoot critical manufacturing processes with appropriate communication and documentation (e.g., batch records, logbooks, and other related documentation).
- Identify method improvement through workplace layout, machinery layout, and material handling.
- Assist in the set-up of new equipment, ensuring satisfactory standards, training, and operation.
- Attend training classes, workshops, meetings, etc., as required to improve job skills and product related procedures.

Required Education and Experience

- Minimum education requirements include a science related bachelor's degree or relevant work experience.
- At least 2 years of experience working in manufacturing is preferred.

- Must develop knowledge of 21 CFR Part 210 and 211 for cGMP operations.
- Must be capable of wearing all protective gear (gown, hair bonnet, mask, beard cover, gloves, goggles) and maintain good personal hygiene (makeup, jewelry, and other cosmetics are prohibited from the production areas).
- Must be able to perform aseptic gowning and related procedures.
- Must possess strong verbal, written, and oral communication skills.
- Must be able to work independently and with a team.
- Must possess problem-solving skills.
- Ability to recognize priorities and actively make productive use of time to build operational efficiencies.
- Must exhibit punctuality and low absenteeism.
- Able to sit and/or stand 8-10 hours or more per day as needed.
- May need to lift up to twenty-five (25) pounds on occasion.

Competencies
- Communication
- Organizational Skills
- Problem Solving/Analysis
- Results Driven
- Technical Capacity
- Detail Oriented

Supervisory Responsibility
This position has no supervisory responsibilities.

Work Environment
This job operates primarily in a controlled laboratory environment. This position requires the use of standard office equipment, PPE, and frequent standing and walking.

Physical Demands
The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job.
- Able to sit and/or stand 8-10 hours or more per day as needed
- May need to lift up to 25 pounds on occasion

Position Type and Expected Hours of Work
This is a full-time position. Because of the nature of the business, work schedules may vary at times.

Travel
No travel is expected for this position.

Disclaimer
The above job description is intended to describe the general nature and level of work being performed by employees assigned to this job. It is not designed to capture or illustrate a comprehensive list of all responsibilities, duties, and skills required of employees assigned to this job.

AAP/EEO Statement
Stokes Healthcare is an Equal Employment Opportunity and Affirmative Action Employer.