

Job Title: Manufacturing Operator



Department: Manufacturing
Reports to: Manufacturing Supervisor

FLSA Status: Non-Exempt
Location: 110 Terry Drive

BASIC FUNCTION: Operators are responsible for operating special purpose machines or industrial equipment to specifications on production basis in typical oral solid dose pharmaceutical manufacturing. Processes include dispensing and weighing of materials, using automatic and semi-automatic equipment for tablet manufacturing, combining materials to make blends and solutions, and packaging of finished product.

JOB RESPONSIBILITIES:

- Ensure the proper set-up and operation of standard pharmaceutical process equipment such as Granulators, Blenders, Mills, Tablet Presses, Tablet Coaters and Packaging.
- Ensures proper execution of Master Batch Records, standard operating procedures and validation protocols.
- Ensures accurate completion of equipment logs and/or lab notebooks.
- Ensures cleanliness and proper assembly of manufacturing equipment per approved procedures (SOP's).
- Weighs out material and components for production batches.
- Interfaces and consults with Analytical Sciences and Quality Assurance personnel.
- Identify and report quality issues
- Must be in compliance at all times by following batch records, SOPs and all company policies
- Perform all in-process testing and inspections as required by the Master Batch Record (i.e. weighing, tablet thickness, tablet hardness, friability, visual inspection, etc.)
- Cleaning and sanitization of manufacturing rooms including walls, floors, and ceilings per current SOPs
- Report accidents and unsafe conditions or unusual circumstances to supervisor.
- Understands and adheres to all cGMP and FDA regulations.
- Responsible for maintaining a neat and orderly work area at all times
- Other duties, which may be assigned from time to time, by management of the company

ESSENTIAL JOB REQUIREMENTS AND QUALIFICATIONS:

- High School Diploma or equivalent or technical school certificate
- 1-3 years solid dose production operator experience or previous experience working in a regulated environment (GMP or FDA)
- Excellent written and verbal communication skills.
- Ability to read and comprehend SOP's, Batch Records and training documents.

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- Ability to multi-task effectively
- Excellent interpersonal skills and ability to effectively interact with different functional groups.
- Must be able to stand for an 8 hour shift and lift, push or pull up to 50 pounds.
- Ability to wear any type of protective equipment

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.