

## Senior Formulation Scientist



Department: Research & Development  
Reports to: Research & Development Director

FLSA Status: Exempt  
Location: 110 Terry Drive

**BASIC FUNCTION:** Lead a team of formulation scientists with the design and development of formulations and processes by QbD, manufacturing of exhibit batches, preparation of product development reports, support of all necessary documentation for ODR and regulatory submissions.

### **JOB RESPONSIBILITIES:**

- Formulation Development of solid dose pharmaceutical products that include Sustained / Extended / Delayed Release dosage forms.
- All aspects of the product cycle for new products from the lab bench to commercialization.
- Leading projects as the lead technical expert in the area of formulation development.
- Facilitating a rapid cycle time for the development and filing of ANDA's, NDA's and 505(b)2 regulatory filings.
- Creating, reviewing, and revision of Product Development SOP's, and providing training to different areas and levels in the organization.
- Researches various product ingredients and determines which are suitable for use in the product under development.
- Writes product development experimental batch records which include amount and type of ingredients express instructions for their processing and blending and instructions for the final tableting/filling of the dosage form.
- Submits samples to the laboratory including instructions for their testing
- Researches equipment for use in the laboratory
- Analyzes lab data and makes changes to subsequent experiments accordingly
- Interacts with manufacturing and laboratory departments to facilitate completion of work
- Handle all new and developing products
- Handle small scale batches
- Finish product sampling for Quality Control and Quality Assurance
- Calibrations and Maintenance of all machines such as fluid bed dryers, tablet presses
- Research and gather information in a timely manner
- Handle and complete special projects as required
- Have a logical, methodical approach to work, and be precise when taking measurements and recording figures

### **ESSENTIAL JOB REQUIREMENTS AND QUALIFICATIONS:**

- Manage tight timelines, multiple projects, duties and assignments.
- Advanced knowledge of theories, practices and principles of physical pharmacy, pharmaceuticals, pharmacokinetics, bio-pharmaceutics and statistical designs

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- Ability to efficiently handle pharmaceutical unit operations, such as fluid bed coater, compression, roller compaction, high shear granulation, particle and tablet coating, encapsulation and packaging.
- Current knowledge of product formulations, product stability, packaging, and FDA submission methods, practices and regulatory requirements.
- Product design of controlled release dosage forms, working knowledge of multi-particulate systems, matrix systems, diffusion controlled and osmotically engineered pharmaceutical dosage forms. Experience with other dosage forms is a plus.
- Ability to perform mathematical calculations, operations and basic statistics.
- Capability to research and utilize current and new technology.
- Experience with multiple bench top, pilot and manufacturing equipment.
- Excellent interpersonal and communication skills

### EDUCATION & EXPERIENCE:

- Master of Science (M.S.) in Pharmaceutical Technology or Chemistry, a Ph.D. degree is preferred.
- Previous Pharmaceutical Industry experience with 5 – 10 years developing various dosage forms
- Experience with Solid Oral Dosage forms is a must

**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.