

Formulation Scientist:

Key Responsibilities:

Your Role and Responsibilities include but not limited to,

- Developing complex pharmaceutical products, leading to successful NDA/ANDA filings and approval in a timely manner.
- Managing and scheduling multiple projects, setting objectives and prioritizing activities to meet the milestones in a fast pace environment.
- Designing, formulation and process development for various drug delivery systems from project initiation to commercialization by following appropriate GMP regulations and safety requirements.
- Preparation of product manufacturing, batch records and protocols for different product development stages, including from R&D prototype formulations to process validations following SOPs and procedures; ensuring the detailed record and data keeping.
- Characterization of APIs, excipients and in process products; analysis of in-process samples or in-process products based on protocols and QbD concept, preparing various formulation samples to support cross-functional programs as needs.
- Setting-up and cleaning equipment for experiments by following the SOPs, maintaining formulation Lab in a clean and safe working environment.
- Establishing documentation management systems for CMC development and meeting FDA GMP, regulatory requirement and FDA onsite inspections.
- Ensuring all regulatory documents in compliance with SOPs, FDA Regulations and cGMP policy where applicable.
- Maintaining formulation development notebook document work.
- Maintaining compliance with GMP, SOPs and DEA regulations.

Qualifications and Requirement

- Master or Ph.D. (preferred) in Pharmaceutical Sciences, Chemical Engineering, Biochemistry, or related discipline,
- Minimum 5 years of proven track experience in ANDA/NDA pharmaceutical product development from “End to End” is required.
- In-depth theoretical and hands on experience in pharmaceutical technologies and equipment for various dosage forms (oral solids, liquids and injectibles), especially focused on MR/IR delivery systems.
- Expertise in product Deformation & Reverse Engineering; familiar QbD concept for product development.
- Demonstrate ability to be self-motivated with an inherent winning can-do attitude.
- Flexible working hours.

Physical Demands/Factors:

- While performing the duties of this job, the employee is regularly required to stand. The employee is frequently required to sit, walk, talk, hear, handle or feel tools or controls. The employee is occasionally required to reach with hands and arms, stoop, crouch, climb or balance, kneel. The employee must occasionally lift and or move up to 20 pounds. Specific vision abilities required by this job include close vision, distance vision and peripheral vision.
- 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. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

This job description is not all-inclusive. It acts as a guideline and is subject to change over time. Additional duties may be assigned based on business needs.

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