



PraNa Biosciences, Inc.
17 Briden Street, Worcester, MA 01605
Phone: 1-508-752-5559

Job Description: Lead Formulation Scientist

Dept: Formulation Development

Company – PraNa Biosciences Inc.

Responsibilities and Duties:

Design formulations and process for complex and challenging compounds in oral, semi solid parenteral and others dosage form development, process.

Developing complex pharmaceutical products, leading to successful NDA/ANDA filings and approval in a timely manner

Actively involved in project management and product development strategies and handle all technical, legal, and regulatory aspects of development projects.

Managing and scheduling multiple projects, setting objectives and prioritizing activities to meet the milestones in a fast pace environment.

Preparation of 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.

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.

Required Skills and Experience:

Master or Ph.D. (preferred) in Pharmaceutical Sciences, Chemical Engineering, Biochemistry, or related discipline,

Minimum 12-15 years of proven track experience in ANDA/NDA pharmaceutical product development from “End to End” is required.

Industrial experience in oral, parenteral, or others dosage form development, process optimization and scale-up



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Experience in Innovative approaches to solving formulations challenges and formulation technologies to improve solubility and bioavailability of poorly water-soluble drug is preferred.

Strong scientific expertise, demonstrated by published scientific articles in peer-reviewed journals, society participation, regulatory filings and patents. Proficient in using computer to write and review technical reports and scientific judgment in data evaluation.

Excellent communication skills, problem solving, critical thinking, and organization skills. Ability to work in a fast-paced organization with diverse project teams and personnel.

In-depth theoretical and hands on experience in pharmaceutical technologies and equipment for various dosage forms (oral solids, semi solids, liquids and injectables), especially focused on MR/IR delivery systems.

Demonstrate ability to be self-motivated with an inherent winning can-do attitude.

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 projects and business needs.