Principle Scientist/Director/Senior Director/Vice President in Pharmaceutical R&D

About Ascendia Pharmaceuticals:

Ascendia Pharma is a dynamic, fast growing specialty pharmaceutical company located in North Brunswick, NJ. The company's primary focuses are research & development of innovative specialty pharmaceuticals (e.g. enhanced formulations of existing medicines, new chemical entities (NCE), and niche injectable pharmaceuticals) and pharmaceutical R&D development services. We leverage our proprietary drug delivery technologies including nano-emulsions, amorphous solid dispersions, and nano-particle formation. The mission of our company is to create advanced medicines to help patients prevail over their disease and enhance their quality of life.

About the Position:

Ascendia Pharma is looking for a formulation leader for its Pharmaceutical R&D team. This position will manage all activities related to formulation development under discovery and development settings. The successful candidate will be actively involved in developing formulation and manufacturing processes and transferring these methods and processes to drug product manufacturers. The candidate will work closely with external product manufacturers to manufacture the formulations throughout all phases of drug development. The candidate will build a group of highly qualified scientists and will be responsible for supervising and mentoring their career development. The ability to work effectively in a collaborative, interdepartmental team environment is essential to this role with the expectation that this scientist will interact with all disciplines of drug development, including discovery, pre-clinical, clinical, pre-formulation, analytical R&D, and regulatory. A thorough understanding of pharmaceutical development process from discovery to commercialization is highly desirable.

Principal Responsibilities:

Design formulations and processes for complex and challenging compounds.

Provide strategic direction and guidance to discovery and development programs

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

Evaluate, select and manage appropriate CMOs and cGMP manufacturer of drug product for development projects.

Participate in discovery and clinical development project team to inform and update the team on the status of all active projects

Build the formulation development infrastructure and recruit, manage and provide mentoring to highly qualified scientists and associate scientists.

Write and review CMC reports and documentation for regulatory filings.

Keep current with regulatory guidelines, technical innovations, and new developments within pharmaceutical industry.

Qualifications

The position requires a Ph.D. degree in Pharmaceutics, Physical Pharmacy, Chemical Engineering, or Pharmaceutical Sciences with relevant pharmaceutical industrial experience. A candidate with a Master degree in a relevant field and extensive industrial experience will be also considered.

Demonstrates expertise in solid oral or parenteral dosage form development, process optimization and scale-up.

Successful development experience in innovative approaches to solving formulation challenges, and in formulation technologies to improve solubility and bioavailability of poorly water soluble drugs is preferred.

In-depth understanding of pre-formulation, formulation, and biopharmaceutics principles required to get a drug from discovery through clinical development is desirable.

Strong scientific expertise, demonstrated by published scientific articles in peer-reviewed journals, society participation, regulatory filings and patents. Proficient in writing and reviewing technical reports, and excellent scientific judgment in data evaluation.

Experience in managing scientific personnel and multiple projects, and external CMOs.

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

Working knowledge of cGMPs, Standard Operating Procedures, FDA/EMA/JP/SFDA regulations, and safety will be a plus.

Knowledge in pharmaceutical product development, CMC regulatory requirements, project and line management; and capability to collaborate with colleagues.

Flexibility for domestic and international travel, and fluency in English and Mandarin are desired.

EEO/AA M/F/V/D

To apply, please submit your CV or resume to HR@ascendiapharma.com