

Principal or Senior Principal Formulation Scientist

Humanwell Pharmaceuticals US, St. Louis, MO

Summary:

Humanwell Pharmaceutical US, Inc. is a Ballwin, MO-based pharmaceutical research and development company which focuses on research and development of novel therapeutics for unmet medical needs.

The laboratory is currently seeking a highly motivated Principal or Senior Principal Formulation Scientist with proven track record in complex injectable product development. This role will be leading pharmaceutical development activities on multiple projects. The individual will perform and oversee all aspects of product development including pre-formulation, formulation, technology transfer, scale-up, and registration batch manufacturing activities. The individual will work in multidisciplinary teams and with CRO/CMOs in support of drug product development, manufacturing, and regulatory filing.

The title will be determined based on qualifications.

Job Responsibilities

- Lead formulation or entire CMC development of complex injectable products of new and existing chemical entities.
- Design and conduct pre-formulation, formulation, process, sterilization, scale-up, stability, and container closure studies.
- Apply scientific fundamentals and creative problem-solving skills to solve complex technical issues.
- Prepare technical reports, presentations, and CMC documents to support regulatory submissions.
- Represent formulation or CMC in cross-functional teams, collaborate with internal and external stakeholders and partners, such as preclinical, clinical, and manufacturing.
- Define scope, timeline, and resource needs of functional activities and keep team on schedule.
- Identify and manage external vendors and partners when needed.
- Participate in evaluation of new product opportunities.
- Follow pharmaceutical cGMP practices and other relevant regulatory guidelines.
- Develop and mentor junior scientists.
- Extended work hours may be occasionally required based on project needs.
- Ability to travel domestically and internationally up to 25% of time.
- Additional duties and assignments as needed.

Principal Formulation Scientist

Required Qualifications and Skills:

- Ph.D. in Pharmaceutical Science, Chemical Engineering, Chemistry, or related disciplines, with at least 5 years of relevant experience in a pharmaceutical R&D environment. Strong candidates with combinations of education and experience will be considered.
- Hands-on experience in lab and commercial-scale development of complex injectable products.
- Demonstrated success in moving R&D project through multiple development stages.
- Extensive knowledge in advanced drug delivery systems and their pharmaceutical applications, such as emulsions, suspensions, polymer, nanoparticle, and colloidal systems.
- Familiar with common and advanced physicochemical characterization techniques used in complex product development.
- Familiar with regulatory requirements, such as FDA guidances and ICH guidelines.
- Demonstrate ability to work as part of a cross-functional team.
- Ability to communicate in an open, clear, timely and consistent manner.
- Ability to thrive and to lead in an environment with rapidly changing priorities.

Senior Principal Formulation Scientist

Required Qualifications and Skills:

In addition to the qualifications above:

- Ph.D. in Pharmaceutical Science, Chemical Engineering, Chemistry, or related disciplines, with at least 7 years of relevant experience in a pharmaceutical R&D environment.
- Demonstrated success in product development from early stage to regulatory filing.
- Experience leading functional teams or cross-functional teams highly desirable.

Job Type: Full-time

Job Location: Ballwin, MO