Humanwell Pharmaceutical US, Inc.
421 Sovereign Court, Ballwin, MO 63011
Phone (636)-220-3636
www.humanwellus.com

Senior or Principal Formulation Scientist – Oral Product Development

Humanwell Pharmaceuticals US, St. Louis, MO

Interested candidate, please submit resumes to email: Info@humanwellus.com

Summary

Humanwell Pharmaceutical US, Inc. is a St Louis, MO-based pharmaceutical research and development company which focuses on research and development of novel therapeutics for unmet medical needs. At Humanwell, we work towards improving patients' quality of life and are committed to creating a healthier world of tomorrow. We are looking for people who are passionate about making people's lives better.

With Humanwell US's recent expansion, we are currently seeking a highly motivated Senior or Principal Formulation Scientist with proven track record in various dosage forms development, especially in oral 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, registration batch, and facilitate regulatory fillings of ANDAs and 505(b)(2). 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 product development from initial R&D up to final product approval with minimal guidance, including pre-formulation, formulation, process, stability, and container closure development studies by QbD for oral dose pharmaceutical products that include IR and ER tablets/capsules (single- or multiple-layer matrix tablets, gastro-retentive tablets, etc.), liquid dosage forms (solution and suspension), and ADF (abuse deterrent formulation) dosage forms.
- Apply scientific fundamentals and creative problem-solving skills to solve complex technical issues, including complex formulation, stability, and manufacturing 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 manufacturing and clinical BE.
- 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.

Senior Formulation Scientist Required Qualifications and Skills:

- Ph.D. in Pharmaceutical Science, Chemical Engineering, Chemistry, or related disciplines, with at least 3 years of relevant experience in a pharmaceutical R&D environment. Strong candidates with combinations of education and experience will be considered.
- Demonstrated success in moving R&D project through multiple development stages.
- In-depth, hands-on experience in controlled release dosage forms, working knowledge of matrix systems, extended release coating systems, multiparticulate systems, osmotically engineered pharmaceutical dosage forms and abuse deterrent formulations. Experience with other complex dosage forms (liquid, topical, nasal, etc.) is a plus.
- Familiar with regulatory requirements, such as FDA guidances and ICH guidelines.
- Demonstrate ability to work as part of a cross-functional team.
- Demonstrate leadership ability and excellent oral and written communication skills in an open, clear, timely and consistent manner.
- Ability to thrive and to lead in an environment with rapidly changing priorities.
- Qualified candidate must be authorized to work in the USA.

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 5 years of relevant experience in a pharmaceutical R&D environment.
- Demonstrated success in product development from early-stage to regulatory filing.
- Hands-on experience in lab and commercial-scale development of complex oral products. Experience in other dosage forms is a plus.
- Extensive knowledge in advanced drug delivery systems and their pharmaceutical applications on ANDAs and 505(b)(2).
- Experience leading functional teams or cross-functional teams is highly desirable.

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Job Type: Full-time

Job Location: Ballwin, MO

At Humanwell, all of our employees are part of a team that cares about them. We all share the purpose of making the world a healthier place. We hope that you seek to join us on our journey as we develop medicine and improve global human well-being.