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

Associate Director for Oral Product Development

Humanwell Pharmaceuticals US, St Louis, MO

Interested candidate, please submit resumes to email: hr@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 to address unmet medical needs. At Humanwell, we work towards improving patients' quality of life and are committed to creating a happier and healthier world

This associate director for product development position will perform and/or oversee research and development activities related to new drug products and support existing drug products for oral solid, injectable, and other complex dosage forms. The successful candidate will perform and/or oversee all aspects of product development including pre-formulation, formulation, scale-up, and technology transfer activities. The successful candidate will design studies, analyze and interpret data of varying complexities, and make recommendations. Prepare necessary regulatory documents for submissions.

Primary Duties and Responsibilities

1. Accountable for CMC development of oral solid and/or injectable products of ANDA and 505b2.
2. Design and conduct pre-formulation, formulation, process, sterilization, scale-up, stability, and container closure development studies
3. Apply scientific fundamentals and creative problem-solving skills to solve complex formulation, stability, manufacturing, and other technical issues.
4. Identify and manage CRO/CDMO organizations to maximize development efficiency and productivity.
5. Manage technology transfer, scale-up and registration batches manufacturing activities.
6. In-depth understanding of bioequivalence study design and analysis of pharmacokinetics data.

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7. Prepare technical reports, presentations, and CMC documents for ANDAs, NDAs, and other regulatory dossiers.
8. Manage CMC development activities and author /review CMC sections to support regulatory submissions
9. Prepare responses for CMC information requests/deficiencies and developing CMC strategies in support of biowaiver and reduced stability testing.
10. Lead new product development projects from the lab bench to commercialization independently.
11. Review all related technical documents for new project opportunities.
12. Screen and identify key vendors for DMF API, excipients, tooling and package materials etc.
13. Identify functional activities for projects and provide estimates for timelines/resource requirements; coordinate activities in functional area; keep functional activities on schedule to facilitate regulatory filling of ANDAs and 505b2.
14. Represent the formulation function in cross-functional project teams.
15. Coordinate with various groups including analytical method development, quality control, regulatory affairs, quality assurance, production and purchasing departments etc. to expedite the development and approval of new products by FDA.
16. Review and revise department SOPs and other technical documents.
17. Additional duties and assignments as needed.

Required Qualifications and Skills:

1. PhD. degree in Pharmaceutical Science, Chemical Engineering, Chemistry, or related science with a minimum of 5 years of pharmaceutical industry experience or,
2. MS degree in Pharmaceutical Science, Chemical Engineering, Chemistry, or related science with a minimum of 8 years of pharmaceutical industry experience in a pharmaceutical R&D environment.
3. Experience in generic and/or 505b2 NDA product development is a must.
4. Strong technical background in pharmaceutical science, physical chemistry, and polymer science.
5. In-depth, hands-on product development experience at lab and commercial scale in oral solid dosage forms and/or injectables. Experience with other complex dosage forms (long acting injectables, nasal, topical, etc.) is a plus.

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6. Extensive knowledge in advanced drug delivery systems and their pharmaceutical applications, such as emulsions, suspensions, polymer, nanoparticle, and colloidal systems.
7. In-depth, working knowledge of pharmaceutical dosage products, advanced drug delivery systems, and pharmacokinetics.
8. Familiar with regulatory requirements, such as FDA guidance and ICH guidelines.
9. Demonstrate leadership ability and excellent oral and written communication skills.
10. Experience to handle DEA controlled substance is preferred.
11. Demonstrated ability to collaborate and lead cross-functional project teams.
12. Qualified candidate must be authorized to work in the USA

Physical Demands/Environmental Conditions:

1. The laboratory facility is air conditioned and environmentally controlled.
2. Employees are required to wear eye protection and lab coats while in the lab area.
3. The employee occasionally lifts and/or moves up to 25 lbs. and may work with toxic or caustic chemicals.
4. Ability to travel domestically and internationally up to 25% of time.
5. Must pass background clearance and drug testing.

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.