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

POSITION DESCRIPTION

Title: **Senior Formulation Scientist**

Position Type: Full-Time

FLSA Status: Exempt

Job Code: HM-015

Department: Oral Product Research and Development.

JOB DESCRIPTION

Summary

Humanwell Pharmaceutical US, Inc. is a St Louis, MO-based pharmaceutical research and development company that focuses on the 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 Principal Formulation Scientist with a proven track record in various dosage forms development, especially in oral product development. This role will be leading pharmaceutical development activities on multiple projects.

Essential Functions

1. Design and conduct pre-formulation, formulation, process, stability, and container closure development studies by utilizing QbD (quality by design) approach to develop oral solid dose pharmaceutical products, including Sustained / Extended / Delayed Release dosage forms;
2. Provide technical stewardship of formulation design, equipment selection, and scale-up readiness at third parties in support of Current Good manufacturing practice (cGMP) drug product manufacture on multi-kilogram scale.
3. Lead new product development project from the lab bench to commercialization independently, including reviewing all related technical documents for new project

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

opportunities, screening and identifying API suppliers through Drug Master File (DMF), excipients, tooling, and packaging vendors.

4. Prepare batch manufacturing records, product development reports, and Quality overall summary (QOS) documents to facilitate the regulatory filing of ANDAs (Abbreviated New Drug Application).
5. Define scope, timeline, and resource needs of functional activities and coordinate activities in the functional area to keep project timelines on schedule.
6. Writes protocols and batch records to carry out process development and evaluation work, scale up and pivotal batch manufacturing for Abbreviated New Drug Applications (ANDAs) submission to regulatory agency.
7. 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 the FDA.

Minimum Requirements

Education/Experience:

- MS degree in Pharmaceutical Science, Chemical Engineering, Chemistry, or related field with a minimum of 8 years of pharmaceutical industry experience.
- Proficient in fornulations: controlled release dosage forms, extended-release coating systems, and Bilayer/triple layer Tablets formulations.
- Proficient in lab/production equipment: Multilayer compression machines, large scale perforated coating pans, Air jet mill(micronizer), High shear granulator with high viscosity binders, and sachets filling machines.