POSITION DESCRIPTION

Title: **Senior Product Development 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 **Senior Product Development Scientist** with a proven track record in various dosage forms development, especially in oral product development. The individual will perform and oversee all aspects of oral pharmaceutical product development including pre-formulation, formulation, technology transfer, scale-up, registration batch, and facilitate regulatory filling 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.

Essential Functions

1. Lead oral pharmaceutical product development from initial R&D to final approval including:

   1) Literature and patent research, screening and identifying API suppliers through Drug Master File (DMF), sourcing excipients, tooling, and packaging vendors.

   2) Design and conduct pre-formulation, formulation, process, stability, and container closure development studies by utilizing Quality by Design (QbD) approach to develop generic oral solid dose pharmaceutical products, including Immediate/Extended/Delayed Release dosage forms.

2. Conduct hands-on lab R&D activities on various formulations including but not limited to immediate- or extended- release dosage forms (tablets/powders), extended-release coating systems, bilayer/triple layer tablets, filling and packaging by using pharmaceutical equipment such as high shear granulator, mill, bilayer/triple layer tablet compress, coater, sachets filling/packaging machine.
3. Prepare technical documents including preparing SOPs, batch records, in-process protocols and stability protocols to carry out formulation and process development, and ensure the timely execution of scale up and registration batches in compliance with the FDA guidline.
4. Propose final formulation design, equipment selection and manufacturing process for scale-up trials and collaborate/manage CMO for scale-up trials and CROs for clinical studies in support of Current Good Manufacturing Practice (cGMP) drug product manufacture on commerical scale.
5. Prepare product development reports (PDR), quality overall summary (QOS), proposed commercial batch potocols, and other formulation related technical documentsto facilitate the regulatory filing of Abbreviated New Drug Application (ANDA).
6. Coordinate with various groups, including analytical, quality control, regulatory affairs, quality assurance, production and purchasing departments, etc., to expedite the development and approval of new products by FDA.

Minimum Requirements

Education/Experience:

- MS degree in Pharmaceutical Science, Chemistry, or related field with a minimum of 3 years' experience in oral product research and development in the pharmaceutical industry.
- Must have working knowledge of all the formulations, lab and production equipment as described in the above job description to perform these tasks.