

Job Code:..... 101596
Position # (NUNC) . (E)
Developed by: CCM; JL
Reviewed byDLJ
Approved by.....AMC
Date: 10/20/22

UNIVERSITY OF RHODE ISLAND
POSITION DESCRIPTION

TITLE: Pharmaceutical Development Scientist, Pharmaceutical Development Institute (PDI)

DIVISION: Academic Affairs (College of Pharmacy: PDI)

REPORTS TO: Director, PDI

GRADE: 14

SUPERVISES: Professional staff and graduate assistants

BASIC FUNCTION:

Responsible for the end-to-end drug product development of solid oral dosage forms. Assess and/or determine physical and chemical characteristics of drug substances that are applicable for drug product development. Thoroughly understand excipient selection necessary to facilitate the development of robust, stable, scalable, and reproducible formulations for solid oral dosage forms. Explore and characterize early drug product formulations with the intent to advance one or more into early phase clinical trials, including support and participation in GMP manufacturing operations. Work closely with Analytical Development, Quality Control, Quality Assurance, and representative(s) of partner companies. Work with instruments and equipment in a GMP pharmaceutical laboratory/manufacturing environment.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

Independently design and develop stable formulations for solid oral dosage forms, including selection of excipients and determination of manufacturing process unit operations.

Perform hands-on experiments with solid dose form unit operations, including, but not limited to, blending, wet and dry granulations, wet and dry milling, fluid-bed technology, encapsulation, tableting, coating, and packaging.

Perform hands-on characterization and/or in-process control tests, including, but not limited to, weight, hardness, thickness, friability, density, particle morphology, particle size distribution, loss on drying, and disintegration.

Perform hands-on characterization studies (e.g., compatibility, sensitivity, and stability) on drug substances to assess and propose early formulation candidates, as necessary.

Independently design and perform sophisticated experiments using Design of Experiments (DOE), statistical tools for data analysis, and principles of quality-by-design.

Design development stability strategies, including selection and technical justification for packaging materials.

Support and participate in GMP manufacturing, packaging, and/or labeling operations.

Keep up to date on technology advancements and make recommendations to expand in-house technology capabilities (formulation and process), including defining user requirements and procurement of equipment/instrumentation necessary to perform formulation and process development activities.

Document all work in laboratory notebook(s) or other acceptable forms (e.g., batch records).

Write and review SOPs, development protocols, and technical reports.

Write procedures and execute qualifications for equipment and instrumentation, as needed (e.g., IQ, OQ).

Lead or contribute to invention disclosures and patentable advancements.

Assist with troubleshooting, deviations, and investigations, as requested.

Procure supplies necessary to perform work, including reagents, components, laboratory supplies, etc.

Build and maintain a strong cooperative working relationship with colleagues in Analytical Development, Quality Control, Quality Assurance, and partner companies.

Summarize work and report status and issues in a timely manner.

Utilize Microsoft Office software (e.g., Word, Excel, PowerPoint.)

Train and mentor junior level technicians/scientists, as needed.

OTHER DUTIES AND RESPONSIBILITIES:

Perform other duties as assigned.

LICENSES, TOOLS, AND EQUIPMENT:

Pharmaceutical manufacturing and equipment, personal computers, printers; word processing, database and documentation management, spreadsheet software and related products. Microsoft Office.

ENVIRONMENTAL CONDITIONS:

This position is not substantially exposed to adverse environmental conditions. The position requires that the individual be able to work in a pharmaceutical development and manufacturing facility with exposure to active pharmaceutical substances using personal protective equipment and product protective garb.

QUALIFICATIONS:

REQUIRED: Bachelor's degree in pharmaceutical sciences, pharmaceutical engineering, or related field with five years' experience in pharmaceutical solid oral dose development in the pharmaceutical industry or similar environment, OR Master's degree in pharmaceutical sciences, pharmaceutical engineering, or related field with

three years' experience in pharmaceutical solid oral dose development in the pharmaceutical industry or similar environment; Demonstrated experience in pharmaceutical formulation development for solid oral dosage forms; Demonstrated experience with selection of excipients used for solid oral dosage forms; Demonstrated experience with the operation of equipment used in solid dose formulations; Demonstrated familiarity with the operation of characterization and/or in-process control testing instrumentation used for solid dose formulations; Demonstrated understanding of current FDA regulatory requirements, including GMPs; Demonstrated experience with good documentation practices; Demonstrated experience performing activities following standard operating procedures (SOPs); Demonstrated ability to work both independently and cooperatively in a small laboratory environment; Demonstrated ability to manage multiple priorities and project timelines in a deadline-driven environment; Demonstrated strong verbal and interpersonal communication skills; Demonstrated proficiency in written communication skills; and, Demonstrated ability to work with diverse groups/populations.

PREFERRED: Ph.D. in pharmaceutical sciences, pharmaceutical engineering, or related field; Minimum five years' experience in pharmaceutical solid oral dose development in the pharmaceutical industry or similar environment; Demonstrated knowledge of and familiarity with all aspects of drug development (preclinical, clinical, toxicology, AD/QC etc.); Demonstrated understanding of phase-appropriate approaches to quality pharmaceutical systems; Demonstrated familiarity with analytical attributes and establishing drug product specifications; and, Demonstrated knowledge of regulatory submissions, including ability to write/review/support CMC sections of regulatory submissions for clients, if requested.

ALL REQUIREMENTS ARE SUBJECT TO POSSIBLE MODIFICATION TO REASONABLY ACCOMMODATE INDIVIDUALS WITH DISABILITIES.

