Job Code: 101477
Position #: PSA .(E)
Developed by: CCM
Reviewed by: DLJ, LK
Approved by: . . . LK
Date: 07/21; 9/29/21

UNIVERSITY OF RHODE ISLAND
Position Description

TITLE: Specialist, Manufacturing / Pharmaceutical Development Institute (PDI)

DIVISION: Academic Affairs (College of Pharmacy)(PDI)

REPORTS TO: Director, PDI; Manager Operations, PDI

GRADE: 14

SUPERVISES: Students, Manufacturing and Lab Assistants

BASIC FUNCTION:

Work hands-on with all equipment used to manufacture solid oral dosage forms, including unit operations such as dispensing, blending, milling/screening, granulation, drying, tableting, encapsulation, coating, and packaging. At a new facility with new equipment, establish operational competency with all equipment, write Standard Operating Procedures (SOPs) for equipment operation, maintenance, calibration, and cleaning, execute equipment and facility IQ/OQ protocols (as needed), and perform GMP pharmaceutical manufacturing operations.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

Perform hands-on operations for pharmaceutical manufacturing of solid oral dosage forms, including, but not limited to, dispensing, blending, milling/screening, granulation, drying, tableting, encapsulation, coating, and packaging.

Manufacture placebo and active drug product batches (under GMP conditions).

Perform test methods for characterization or powders and dosage forms, such as harness, thickness, friability, disintegration, particle size distribution, moisture content, bulk and tap densities, and surface area.

Perform equipment set-up, break-down, and cleaning, including appropriate care and storage of all change parts.

Ensure the facility and equipment are operationally ready, clean, and maintained per the SOPs and client requirements.

Ensure the facility and operations within it are safe.

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

Assist and contribute to studies and/or activities necessary for formulation/process optimization and continuous improvement to assure robust and cost-effective manufacturing processes.

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

Execute qualification protocols, as needed (*e.g.,* IQ, OQ).

Establish and maintain SOPs for all operations, cleaning, and maintenance.

Establish and maintain batch records.

Understand and practice good documentation practices.

Understand and practice current Good Manufacturing Procedures (cGMP).

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

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

OTHER DUTIES AND RESPONSIBILITIES:

Perform other duties as assigned.

LICENSES, TOOLS AND EQUIPMENT:

Laboratory and pharmaceutical equipment, personal protective equipment, GMP Clean Room, pharmaceutical supplies, instrumentation, personal computers, printers; word processing, database management and spreadsheet software. Microsoft Office. Personal protective equipment.

ENVIRONMENTAL CONDITIONS:

This position may be exposed to chemicals, steam, pressurized vessels, and rotating equipment.

QUALIFICATIONS:

REQUIRED: Bachelor's degree; Minimum of four years' experience in the pharmaceutical industry; Demonstrated experience with formulations and processing of solid oral dosage forms; Demonstrated experience with pharmaceutical processing equipment for solid oral dosage forms; Demonstrated ability to set-up, operate, and troubleshoot equipment; Demonstrated ability to use personal protective equipment, as required; Demonstrated experience executing qualification protocols and SOP; Demonstrated experience with pharmaceutical GMPs (as related to solid oral dosage form manufacturing); Demonstrated ability to prioritize in a deadline-driven environment; Demonstrated experience with Microsoft Office; Demonstrated strong verbal and interpersonal communication skills;

Demonstrated proficiency in written communication skills; and, Demonstrated ability to work with diverse groups/populations.

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