Job Code: 101497
Position #: NUNC (E)
Developed by: CCM
Reviewed by: DLJ, LK
Approved by: . . . LK
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UNIVERSITY OF RHODE ISLAND
Position Description

TITLE: Associate Director**,** Analytical Development/Quality Control Laboratory, GMP Operations

DIVISION: Academic Affairs (College of Pharmacy: Pharmaceutical Development Institute)

REPORTS TO: Executive Director, PDI

GRADE: 16

SUPERVISES: Lab Associates, Lab Assistants, QA/QC personnel

BASIC FUNCTION:

Responsible for the operational leadership and management as well as for building the necessary infrastructure for operation of the AD/QC laboratory. Responsible for the establishment and maturation of processes and procedures for the AD/QC function, particularly given the newness of the facility and its instruments. Establish operational competency with all instruments, write SOPs for instrument operation, maintenance, and calibration, execute instrument IQ/OQ protocols (as needed), and perform testing to support solid oral dosage forms, including development, release, and stability testing. In addition, play a key role in analytical methods development and be thoroughly familiar with USP testing requirements.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

Establish and direct a fully functional AD/QC laboratory function, including developing operational competency with existing instruments and writing procedures.

Work closely with Formulation/Process Development, GMP Manufacturing, Quality Assurance, and clients.

Recommend instrument, equipment, and staff requirements commensurate with project workload.

Identify third-party testing laboratories to supplement capabilities unavailable at the PDI (*e.g.,* microbiological testing).

Develop and manage systems for calibration, preventive maintenance, OOT/OOS, etc.

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

Perform testing of development, in-process, release, and stability samples.

Provide support to OOT/OOS, root cause, and CAPA investigations.

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

Review data to ensure compliance with appropriate procedures, protocols, and specifications.

Author technical documents, including methods, protocols, reports, and specifications.

Understand, establish, and practice good documentation practices.

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

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

Direct and instruct all associates, assistants, and QA/QC personnel

Work with Executive Director to conduct strategic growth & management plans including revenue potentials and staffing needs.

Direct and manage stability chambers and sample storage.

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.

ENVIRONMENTAL CONDITIONS:

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

QUALIFICATIONS:

REQUIRED:

Bachelor's degree with a minimum of ten years' experience in a pharmaceutical AD and/or QC laboratory environment, OR, Ph.D. with a minimum of five years' experience in a pharmaceutical AD and/or QC laboratory environment; Demonstrated hands-on experience with analytical instruments (i.e., HPLC, Karl Fisher, dissolution, and disintegration); Demonstrated ability to set-up, operate, and troubleshoot instruments; Demonstrated experience with pharmaceutical GLPs and GMPs;

Demonstrated experience with standard operating procedures (SOP) creation and applicable regulatory expectations; Demonstrated familiarity with compendial methods associated with solid oral dosage forms; Demonstrated understanding of phase-appropriate approach to quality pharmaceutical systems; Demonstrated experience with Microsoft Office; Demonstrated ability to work independently; Demonstrated strong verbal and interpersonal communication skills; Demonstrated proficiency in written communication skills; Demonstrated ability to manage and work in a small laboratory environment; Demonstrated ability to manage multiple priorities in a deadline-driven environment; and, Demonstrated ability to work with diverse groups/populations.

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