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Position #: PSA(E)
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Reviewed by: . . EPL, LK
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UNIVERSITY OF RHODE ISLAND
Position Description

Title: Manager, Operations/Pharmaceutical Development Institute (PDI)

Division: Academic Affairs (College of Pharmacy)

Reports to: Director, Pharmaceutical Development Institute (PDI) and/or
Director, Finance and Administration, Pharmacy (SSO)

Grade: 15

Supervises: Support Staff, Research Assistants, Research Associates, and Contractors

BASIC FUNCTION:

Responsible for the operation and maintenance of the pharmaceutical GMP laboratories, facilities and equipment in the College of Pharmacy. Assist contract clients, faculty and students in carrying out research and laboratory projects under the strictest of confidentiality. Work hands-on with all equipment used to manufacture pharmaceuticals, including operations such as aseptic processing, dispensing, blending, milling/screening, granulation, tableting, encapsulation, coating, and packaging. Establish and maintain SOPs for equipment operation and facility cleaning/maintenance, establish and maintain manufacturing batch records, and ensure the equipment and facility state of compliance.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

Direct the day to day operation of the facility. Schedule day-to-day operations for the facility. Ensure the facility is operationally ready, clean and maintained per the SOPs and client requirements. Ensure the facility and operations within it are safe. Prepare, maintain and audit safety and security plans in compliance. Ensure that all documentation, records, equipment histories, drawings, and manuals for the facility and equipment are up to date, accessible and

able to be easily audited. Perform and assist with troubleshooting, deviations, and investigations, as requested.

Procure and maintain inventory of equipment and supplies necessary to perform work, including Raw Materials for Human Clinical Trials, excipients, components, precision instruments and general laboratory supplies. Ensure the equipment and facility are in working order for experiments and maintained in a state of cGMP compliance, including: (performing repairs on Pharmaceutical Equipment, provide support for and training on numerous instruments (e.g., Tablet Presses, Viable and non-viable particulate testers); identifying need for new equipment, science support, and upgrades to the facilities; and, writing specifications to obtain, install, and maintain equipment, according to applicable cGMP regulations.)

Perform hands-on operations for pharmaceutical manufacturing of pharmaceuticals, including, but not limited to, aseptic processing, dispensing, blending, milling/screening, granulation, tableting, encapsulation, coating, and packaging.

Perform complex experiments involving use of highly technical instruments and devices.

Manufacture placebo and active drug product batches.

Develop experimental procedures and techniques for resolution of unique project needs.

Perform monitoring of data and observations, recording of results, including photography, video and microscopes.

Summarize and data review, including write-ups and graphing in Excel.

Perform complex test methods for characterization of pharmaceutical raw ingredients, intermediates, powders and dosage forms, such as harness, thickness, friability, disintegration, particle size distribution, moisture content, bulk and tap densities, and surface area.

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

Understand and practice current Good Manufacturing Procedures (cGMP.)

Establish the initial qualification and start-up of the GMP facility; Execute qualification protocols (e.g., IQ, OQ); Establish and maintain SOPs for all operations, cleaning and maintenance; Establish and maintain batch records; and, Understand and practice good documentation practices.

Assist with training courses to ensure safe and effective use of Pharmaceutical Processing equipment and GMP Clean Rooms.

Conduct work in a professional manner with scientific robustness in a highly confidential manner.

Understand facility management, project execution logistics and the conduct of scientific work under cGMP regulations; Exercise sound independent thinking and reach appropriate conclusions with little direct supervision or oversight; Document all work in batch records, equipment logs, laboratory notebook(s) or other acceptable forms; and, Summarize work and report status and issues in a timely manner.

Supervise staff, as required, and oversee contractors performing work within the facility.

Supervise undergraduate and graduate students carrying out their laboratory projects which involve use of very complex, easily damaged and very expensive equipment.

Cooperate with and represent the Director with regulatory bodies to ensure that any requirements for alterations, repair, or modifications are kept at best value consistent with operational and regulatory requirements and cGMP and robust operational practices.

Make decisions that will have a direct effect on the safety of the facility and equipment, as well as the quality and quantity of the services provided to scientific users.

OTHER DUTIES AND RESPONSIBILITIES:

In the Director's absence, act on his/her behalf within the limits of delegated authority.

Serve as a liaison for the Pharmaceutical GMP Facility partnerships

Assist the Director in preparing annual operation schedules, developing operating budgets, writing proposals, and tracking expenditures.

Assist the Director to recruit, interview, and select facility personnel including regular, full time, temporary and intermittent positions.

Assist the Director in planning, coordinating, organizing and conducting workshops and conferences.

Perform related duties as required.

ENVIRONMENTAL CONDITIONS:

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

QUALIFICATIONS:

REQUIRED: Bachelor's degree in technology, engineering, pharmacy or other applied science;

Minimum five years' experience in cGMP pharmaceutical, food, and/or specialty chemical industries; Demonstrated experience with formulations and processing of pharmaceutical dosage forms; Demonstrated experience with pharmaceutical processing equipment for pharmaceuticals, (including the ability to set-up, operate, and troubleshoot equipment); Demonstrated familiarity with all aspects of drug product development and manufacturing, (especially as related to solid oral dosage form manufacturing); Demonstrated familiarity with pharmaceutical GMPs and GLPs; Demonstrated experience working in a pharmaceutical manufacturing facility (or research and development formulation/process development laboratory); Demonstrated familiarity with Process Systems (including experience with Steam, Hydraulics, Chemical Processing and Process Instrumentation); Demonstrated familiarity with Hands on Mechanical Ability (including hands-on mechanical experience with tools); Demonstrated instrumentation experience (including low voltage instrumentation loops); Demonstrated familiarity with applicable international and US regulations pertaining to cGMP Drug and Medical Device manufacture; Demonstrated ability to use personal protective equipment, as required; Demonstrated computer skills (including Excel, Word and PowerPoint); Demonstrated supervisory experience; Demonstrated strong interpersonal and verbal communication skills; Demonstrated proficiency with written communication skills; and, Demonstrated ability to work with diverse groups/populations.

PREFERRED: Master's degree; and, Demonstrated prior knowledge and experience working in a cGMP manufacturing environment.

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