Job Code: ……. 101615
Position # (NUNC) .. (E)
Developed by: .... CCM
Reviewed by: AMC; DLJ
Approved by…….. AMC
Date: ……. 12/12/22

UNIVERSITY OF RHODE ISLAND
POSITION DESCRIPTION

TITLE: Associate Director, Quality Assurance (QA)

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

REPORTS TO: Director, PDI

GRADE: 16

SUPERVISES: QA Specialists, QA Associates

BASIC FUNCTION:

Responsible for leading the Quality Assurance function in support of product quality and quality system compliance. Provide the organization with the leadership required to develop, implement, and maintain quality systems and standards that ensure the overall compliance with regulatory expectations and requirements. Provide strategic and operational leadership for Quality Systems and procedures required to ensure manufacture, testing and supply of products for clinical trials. Ensure QA collaborations with process development, manufacturing, analytical development, quality control, regulatory and program management teams, and with our suppliers/external vendors.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

Lead the Quality Assurance function and team for the PDI.

Develop/improve Quality Systems, programs, and procedures to promote, facilitate, and ensure compliance with regulatory and industry standards and implement risk-based methodologies to improve efficiencies.

Effectively communicate progress and issue resolution to internal/external stakeholders.

Establish and manage the review and audit of internal department processes for compliance with applicable Good Manufacturing Practices (GMP) regulations or guidance.

Ensure an adequate and risk-based audit program.

Ensure an adequate internal PDI personnel compliance training program.

Facilitate the appropriate authoring and implementing of QA Standard Operating Procedures (SOPs) in addition to the review of functional SOPs.

Promote a culture of quality and operational excellence.

Effectively represent the organization's Quality Assurance function.

Facilitate resolution of problems of diverse scope using a high degree of personal judgment.

Assure compliance and consistency to Out of Specification (OOS), Non-Conformances, Investigations, Deviations and Corrective Action/Preventive Actions (CAPAs) throughout vendor network.

Ensure the Quality Systems support the strategic plan to advance the organization's mission and objectives.

Manage the release and disposition of all the organization's products.

Ensure GxP compliant Quality Management practices and procedures at manufacturing and testing sites.

Supervise and manage QA personnel.

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 a scientific discipline (e.g., pharmacy, biology, chemistry, engineering, etc.) with a minimum of 15 years of Quality Assurance experience working in a drug substance and/or drug product development, manufacturing, packaging and testing environment OR a Master’s degree or a PhD degree in a scientific discipline (e.g. pharmacy, biology, chemistry, engineering, etc.) with a minimum of ten years of Quality Assurance experience working in a drug substance and/or drug product development, manufacturing, packaging and testing environment; Demonstrated experience working with Contract Development Manufacturing Organizations (CDMO) and contract laboratories; Demonstrated GMP experience; Demonstrated experience establishing overall Quality systems infrastructure; Demonstrated working knowledge of FDA regulations/guidances and ICH guidances governing cGMPs; Demonstrated experience in practical application of cGMPs in a phase appropriate for Phase I clinical trial materials; Demonstrated experience with vendor audits and Technical Quality Agreements; Demonstrated strong verbal and interpersonal communication skills ; Demonstrated

proficiency with written communication skills; Demonstrated experience with Microsoft Office programs; Demonstrated creative thinking and problem-solving skills; and, Demonstrated ability to work with diverse groups/populations.

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