Position: Senior Supplier Quality Systems Engineer
Location: Maryland Heights, MO

Summary of Position

The Senior Supplier Quality Systems Engineer position is responsible for oversight, administration, and execution of the Supplier Quality Program in compliance with applicable regulations. The position is responsible for Supplier Management, including supplier audits, assessments, Quality Agreements, and corrective actions. The position will require participation in the internal auditing program and supporting site regulatory inspections and customer audits.

Essential Functions

- Manage the Supplier Quality Program in compliance with applicable regulations by working with suppliers to maintain a compliant status.
- Conduct supplier audits, evaluations, and assessments
- Issue supplier complaints and drive for resolution and corrective action.
- Develop and maintain Supplier Quality Agreements
- Perform Quality review and approval of Change Controls.
- Perform statistical evaluations to identify trends and report on Supplier Quality metrics
- Conduct internal quality audits and develop and assess subsequent corrective action recommendations.
- Provide support for FDA or other regulatory inspections and customer audits.
- Provide leadership and coordination on assigned projects.
- Ensure a safe and quality working environment through training, awareness and compliance to regulatory guidelines and procedures.

Requirements

- Bachelor of Science degree in Life Sciences or Engineering required.
- Minimum of 5-8 years of Quality experience in a finished pharmaceutical manufacturing environment with a strong understanding of and exposure to applicable quality systems.
- Minimum of 2-3 years of experience in Supplier Quality Management and supplier auditing.
- Minimum of 2-3 years of experience in supporting on-site regulatory inspections.
- Must have working knowledge in Supplier Quality Management, Supplier Auditing, Supplier Assessment, Supplier Quality Agreements, and Corrective Action.
- Must have a working knowledge of cGMP guidelines and their application in a controlled aseptic environment.

- Must have strong technical knowledge in pharmaceutical quality systems with proficiency in the following: Stability, Change Control, Internal Auditing, Corrective Action Program, Exceptions, Out of Specification Investigations, Customer Complaints, Regulatory Affairs, Document Management, and Annual Product Reviews.
- Must be thoroughly familiar with applicable regulatory guidelines concerning the establishment, validation, and documentation, equipment, processes, and facility systems.
- Must have a working knowledge of Change Management.
- Must have experience with statistical tools.
- Proficient in the use of Microsoft suite of products.

Working Conditions:

- Willingness to work in a plant producing radioactive materials and requiring all employees to participate in safety programs designed to minimize potential and/or actual exposure levels.
- Candidate must be willing to wear a variety of personnel protective equipment.
- Must possess good hand-eye coordination and be able to stand for long periods of time as required by production demand.
- Responsibilities include ability to lift, walk, bend, stoop, push, pull, reach, and climb stairs with or without accommodation, may be required to sit or stand for long periods of time while performing duties.
- Must be able to work outside of regular work hours.
- Willingness to work in a team-based environment.

Disclaimer
The above statements are intended to describe the general nature and level of work being performed by employees assigned to this classification. They are not intended to be construed as an exhaustive list of all responsibilities, duties and skills required of employees assigned to this position.

Equal Opportunity Employer
Curium is an equal opportunity employer and believes everyone deserves respect, dignity and equality. All applicants will be considered for employment without attention to race, color, religion, sex, sexual orientation, gender identity, national origin, veteran or disability status.