St. Renatus

Position Description

Title: Quality Assurance Sr. Manager/Assoc. Director
Reports To: Management
FLSA Status: Exempt
Date Modified: October 4, 2017
Location: St. Renatus, Fort Collins, Colorado

Please send resumes/cover letters to: Recruiting@st-renatus.com

Job Description

This position will provide Quality leadership and oversight of contract manufacturing organizations (CMO) plant operations, ensuring appropriate application and execution of cGMP compliance requirements for combination product. It will also review and revise current quality policies in place and further develop and execute St. Renatus' Quality Management Systems in a manner that ensures successful deliver of cGMP Quality Assurance.

This position performs related tasks that fall under the broad category of Quality Assurance functions. Such tasks will include conducting investigations, determining and/or completing corrective and preventive actions (CAPAs), reviewing Master Batch Records and Master Packaging Records, reviewing Validation Protocols and Qualifications, conducting audits, and evaluating change controls for impact on other cGMP systems. In addition, this position will manage all aspects of the document control and training program and be responsible for authoring standard operating procedures.

Job Responsibilities

- Maintain the cGMP Quality Management System and standards for all aspects of supply chain.
- Provide virtual cGMP Quality oversight for all manufacturing, packaging, storage, and distribution activities to ensure compliance.
- Perform final batch release activities for products manufactured by third parties.
- Review all third parties contracted to perform any functions in support of the cGMP manufacture of clinical supplies and commercial product.
- Identify cGMP compliance gaps or risks.
- Identify and monitor vendor performance metrics and improvement targets.
- Prepare, review, and monitor vendor adherence to Quality Agreements.
- Plan and conduct cGMP audits of manufacturing activities to assess compliance with pertinent regulations, as well as, with company SOPs.
- Review and approve product specifications, stability protocols/data, manufacturing deviations, Corrective Action Preventative Actions (CAPAs), SOPs, Change Control procedures.
- Establish the processes and communications to enable effective delivery on cGMP Quality commitments to build a culture of quality and continuous improvement.
- Ensure prompt communication of cGMP compliance risks to senior management.
- Oversight of pharmacovigilance monitoring program.

- Maintain Quality documentation files.
- Coordinate CMC compliance with Regulatory Affairs, including technical writing and review.
- Execute improvement activities, prepare periodic quality reports, and communicate progress to stakeholders.
- Oversee and facilitate Product Recall System.
- Ensure the periodic assessment of compliance standards and communication of compliance liabilities to senior management. Communicates this assessment on a regular basis.
- Develop and deliver cGMP compliance training and participate with training and development of staff.
- Participate as member of the management team in planning to achieve site goals and objectives; communicates and helps resolve issues or problems that have interdepartmental impacts and in planning to enhance and expand the opportunities
- Determine necessary headcount within Quality area to ensure delivery against goals.
- Management responsibility for non-exempt, exempt and/or supervisory level personnel as the company grows.
- Travel for this position is required (Approx. 10-15% Domestic)

Education / Experience

- BS or BA degree preferred, with emphasis in biosciences, biomedical, or medicine.
- Strong scientific background with at least 8 years of relevant experience in Quality Assurance in the manufacturing environment within the pharmaceutical industry.
- Thorough knowledge of quality systems, compliance regulations, scientific terminology, quality assurance procedures and policies, the use of computer and software developmental methodologies and quality auditing/evaluation techniques.
- Must have experience in the use of controlled documents and related quality systems.
- Previous experience with pharmaceutical production processes and Quality Control analytical methodologies.
- Knowledge of the principles of Quality Management and Continuous Improvement.
- Proven track record of successfully managing Quality Management, Quality Assurance, and Quality Control throughout the lifecycle of a pharmaceutical product.
- Experience in pharmaceutical equipment operation, design and control.
- Experience in leadership roles
- Facility Licensing, Regulatory audits and inspections for combination products.

Competencies

- An investigational nature is essential in evaluating Quality problems.
- Maintains thorough and ongoing knowledge of cGMP methods, compliance and regulatory standards.
- Problem solving skills with the ability to apply logic and assess data to reach decisions and solutions related to compliance and product quality.
- Outstanding verbal, written and interpersonal communication skills. Effective written and oral communication skills is required.
- Demonstrated attention to detail with solid coordinating, task planning and time management skills.

- Must be multi-task oriented and organized to work within numerous systems and programs.
- Demonstrated skills in strategic thinking, problem solving, advising, risk assessment, risk mitigation, decision making, and implemention.
- Strong computer skills including but not limited to Microsoft Office products such as Outlook, Word, Excel, and PowerPoint, and ERP software related to manufacturing and project management.
- Ability to work independently and in a team environment, with strong leadership, negotiation and influencing ability.
- Demonstrated ability to build confidence among contract manufacturers, vendors, peers, customers, and others, quickly.
- A positive, winning attitude.

Essential Physical Requirements

Work environment is office based with some travel and manufacturing floor time. Ability to effectively utilize computer equipment. This position is predominately sedentary but may be required to travel, stand, walk, use hands to finger, handle, or feel, and reach with hands and arms. The ability to hear normal conversation, see documents and computer screens, and talk, are all essential physical requirements.

Note: This description is intended to capture the uniqueness of the position. It is not intended to be an all-inclusive list of every task the incumbent may be asked to carry out. Other duties may be assigned from time to time that differ from the responsibilities listed here.