QA System & Compliance Associate Manager

Department: Quality	FLSA Status: Exempt
Reports to: Manager/Director	Location: 110 Terry Drive

BASIC FUNCTION: The QA System & Compliance Associate Manager ensures quality and compliance of the facility with applicable regulatory requirements. These activities may include reviewing documents and data, conducting process-focused audits and inspections, consulting on quality and compliance issues, maintaining quality databases and performing trend analyses and reporting metrics where required, as well as performing quality and compliance training, as needed. May serve as quality host for client audits and inspections and provide support during regulatory inspections as well as conducting and/or coordinating auditing for vendor quality. Assists with the development of SOPs, specifications, policies or other quality documents as needed.

JOB RESPONSIBILITIES:

- Leader of internal and external cross-functional teams to support manufacturing activities.
- Lead and participate in internal and external audits.
- Provide investigation expertise and technical writing expertise to perform and document process Deviations and Events.
- Thoroughly investigate OOS, OOT, Lab Events/Deviations associated with manufacturing deviations and non-conformances using tools such as Kepner-Tregoe, Fishbone Diagram and to determine potential root cause, corrective and preventative actions, patient risk and product impact.
- Thoroughly document Deviations associated with manufacturing operations.
- Manage the review, tracking, GMP compliance and approval of Change Controls for Production Processes, Facilities and Equipment.
- Manage all CAPA commitments to ensure timely completion of the outlined tasks and their effectiveness.
- Manage the Customer Complaint system for both product and adverse event complaints; ensuring investigations are performed on time and any notifications meet regulatory reporting requirements (i.e. Field Alert Reports (FARs), 3 day and 15 day alerts, etc.).
- Author and review product release memos as required.
- Attend weekly Investigations Review board (IRB) meeting to represent manufacturing investigation status.
- Recommend corrective/preventative measures aimed at improving compliance and reducing repeat occurrences. Partner with area owner to determine if corrective actions adequately addressed root cause of event.
- Review and approve documentation associated with cGMP Compliance. Assess and document product quality impact.
- Provide training and awareness training as needed.
- Develop and maintain site quality metrics in accordance with current FDA guidance.

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- Act as the SME for Deviations, CAPAs, Change Controls, Complaints and Site Quality Metrics during regulatory or FDA cGMP inspections.
- Maintain KPIs related to manufacturing and conformance with SOPs, regulations and Guidelines and present to the Quality Council.
- Develop and maintain monthly Site Quality Council meeting, as well as coordinate and handle weekly Investigation Review Board meetings.

ESSENTIAL JOB REQUIREMENTS AND QUALIFICATIONS:

- Review of Annual product quality reviews.
- Preparation, approval of Standard Operating Procedures.
- Preparation and review Quality Risk Management for process, area and equipment.
- Assist with quality improvement initiatives as needed.
- Assist with development/writing of SOPs or other quality documents and/or reports as needed.
- Provides consultation on quality and compliance topics in the area of expertise.
- Effectively performs a variety of duties, on schedule, with accuracy and competency.
- Serves as an effective member of the Quality team and may serve as a mentor to other Quality employees in the area of expertise.
- Performs other duties as assigned.
- Complies with company polices and SOPs.
- Must have a BS in Chemistry, Microbiology - or related science field, MS preferred
- Minimum of 6+ years of experience in the Pharmaceutical industry
- Good written and oral communication skills
- Experience in statistical analysis, process capability reviews with software
- Ability to act independently
- Excellent interpersonal, verbal and written communication skills

PHYSICAL DEMANDS: While performing the duties of this job, the employee is required to walk, sit, and use hands to finger, handle or feel tools or controls, reach with hands and arms, balance, stoop, crouch, bend, talk and hear. The employee must lift and/or move up to 20 pounds. Specific vision abilities required by the job include close vision, distance vision, color vision, peripheral vision, and depth perception.

The job demands here are representative of those that must be met by an employee to successfully perform the functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions. This job description is not intended and should not be an exhaustive list of all principal job elements essential for recruitment and selection, for making fair job evaluations and for establishing performance standards. The percentage of time spent performing the various job duties is not absolute. The incumbent, who has the right to amend, modify, or terminate this job in part or in whole. This document is not a contract for employment.