JOB DESCRIPTION

POSITION INFORMATION

Job Title:	Quality Control Manager	*Job Requisition #*	
Department:	Quality Assurance	*Report To:*	Director of Quality Management
Location:	STAQ Pharma	*Travel Required:*	10%
Level/Salary Range:	Mid-Level	*Position Type:*	Full Time - Exempt
HR Contact:	Shane Sekiya	*If contract or intern, Length of contract:*	N/A

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Summary	• Lead all Quality Control activities. • Encourage and motivate associates to be successful and focused on Safety, Transparency, Availability, and Quality (STAQ) objectives. • Work with all departments to develop procedures/documentation, implement issue reporting and resolution procceses, implement continuous improvement, and provide support on all Quality Control activities.
Roles and Responsibilities	• Develops, manages, and improves Quality Control processes and procedures to ensure compliance with all applicable laws, regulations, and STAQ Quality standards in support of cGMP standards for pharmaceutical manufacturing (503B). • Focuses on responsiveness, ability to multi-task, attention to detail, effective problem-solving skills, consistent follow-up and ability to make timely and sound decisions. • Oversees process for laboratory analysis of raw materials, in-process QC, finished goods release testing, and reserve sample management. • Participates in internal/external audits and regulatory inspections. • Gains feedback from the clients, attending meetings, submitting reports, and assisting external auditors and inspectors. • Leads the Stability Program including study management, protocol development & evaluation, timely completion of stability tests, data trending, etc. • Identify and devise ways to improve the operations process to ensure higher-quality processes and products. • Ensures investigations related to OOS/OOT, unexpected results, adverse trends, or invalids are performed appropriately and within expected timeframes. • Devises and improves new specifications and procedures for products or processes, and trains staff to use them. • Manages reserve and QC samples for stability and batch release testing • Inspects the final output, comparing it to the requirements, and approving or rejecting final products. • Assists with all aspects of Quality Systems, such as Change Controls, Investigations, Corrective/Preventive Actions, Validation, APQRs, etc. to resolve quality and compliance issues, including data integrity, in a timely manner. • Coordinates operations within the internal laboratory to ensure Environmental Monitoring samples are performed, tested, reviewed, and trended appropriately. • Prepares, reviews, manages, and approves controlled documents (SOPs, protocols, logbooks, reports, etc.) relevant to STAQ QC operations.

	• Manages, mentors, trains, and coordinates QC staff and/or consultants towards proper execution of SOPs & test methods. • Manages the budget for the QC Lab department to meet financial objectives. • Demonstrates a thorough understanding and sound scientific judgment to lead microbiology and chemistry projects, assess analytical outcomes, and direct work actions. • Ensures scientific and compliance-based suitability of analytical methods used for testing materials and products through method transfers and method validations. • Ensures testing equipment is operating correctly and is calibrated and serviced. • Ensures that 3rd party labs meet company requirements and turn-around times. • Develops SOPs, test methods, laboratory investigations, out of specifications, deviations, and CAPAs. • Other duties as assigned.
Qualifications and Education Requirements	• Must have a minimum of 5-7 years of experience with Quality Control (Analytical Chemistry and/or Microbiological Laboratory experience). • B.S. in Chemistry, Microbiology, or equivalent experience, minimum. • Must have sterile pharmaceutical experience including a minimum of 5-7 years sterile QC laboratory supervisory experience, method validation, etc. • Should have proficiency/experience with environmental monitoring program for aseptic facility, personnel monitoring, and qualification program for aseptic facility, etc. • Experience in maintaining cGMP compliance a must. • Must demonstrate understanding and/or working knowledge of cGMP, FDA, USP, ICH, etc. regulations/guidelines. • Experience managing subordinates and projects. • Must have strong analytical and statistical skills.
Preferred Skills	• Industry experience with aseptic operations preferred. • Ability to coordinate multiple priorities in a fast-paced environment. • Solid organizational, analytical, and problem-solving skills. • Strong communication skills with the ability to interact with all levels throughout the organization. • Demonstrated excellent interpersonal skills and flexibility. • Demonstrated ability for successful leadership, influence, and negotiation a plus. • Proficient in using Microsoft Office. • Experience with LIMS or equivalent. • Understanding of Lean Six Sigma principles.
Additional Notes	• This position will work closely with cross functional teams and report quality data to the department heads for each team, as needed. • Please apply via Indeed, LinkedIn, or contact Anil Mathai directly with resume, etc. at amathai@staqpharma.com;