

QUALITY ASSURANCE MANAGER

COMPANY & LOCATION

Our client is a \$200MM+ global leader in the production of pre-moistened wipe products serving four primary markets, i.e., consumer, medical products, institutional/food service and contract packaging. It operates three manufacturing facilities in the U.S. and Europe. This position will be located in Rockland County, NY and will report to the Vice President, Operations. It also interacts with Corporate Sales, R&D, Marketing, Management, Production, Warehouse, and Customers.

COMPENSATION

This position will provide a competitive base salary as well as incentive opportunity and other perquisites.

FUNCTION & RESPONSIBILITIES

Supervise total quality function to advance current methodology. Provide support to corporate function to improve products and/or concepts. Interface with R&D to support product development, improvements and programs. Manage and direct the activities of the Quality Assurance Department to ensure quality and integrity for all products and procedures by complying with all internal and governmental requirements. Provide leadership for compliance with quality standards and regulations by facilitating continuous improvement of process and product quality. Provide efficient processes to maintain and exceed customer expectation.

Supervise and direct the activities of the Quality Systems Manager, the Quality Assurance Department. Interact with professional trade and regulatory bodies outside the facility. Final approval of components, labeling, finished products, operating procedures, work instructions, specifications, analytical test methods, microbiological procedures, validation protocol and results.

Oversee customer complaints, failure investigations, retest investigations, vendor's quality rating, stability programs. Ensure compliance with standards and regulations. Recruit, train, develop and motivate QA personnel. Manage an accurate, reliable, efficient, timely testing function. Witness testing to assure the validity of test processes and test results.

Establish measures for product and process quality and provide data to management. Plan QA department work and set objectives. Evaluate job

performance on a continuous basis and provide timely feedback. Recognize quality performance. Communicate regulatory, technical and quality information to other departments and personnel as required.

Responsible for internal and external customer and regulatory audits. Provide a safe work environment. Identify and implement applicable quality standards. Develop evaluation and acceptance criteria. Develop and evaluate projects from start to completion. Review projects against plans for conformance and effectiveness. Monitor project trends for continuous improvement.

Establish and assess quality measures for product reviews, tests, etc. Inspect and appraise processes to prevent quality failures (internal/external). Oversee the company's Corrective and Preventive Action Program. Ensure cGMP, ISO procedures and work instructions are current and communicated. Lead internal auditing team by providing support and training Lead Auditor. Assess capabilities and training needs and plan for the development of the QA staff to ensure that all required knowledge and skills are available within the function. Design systems, procedures and work instructions to maintain and advance the Quality function in manufacturing.

IDEAL CANDIDATE PROFILE

7-10 years experience working for a manufacturer of FDA-related consumer products (medical devices or OTC products preferable). Three-five years experience managing a Micro Lab, Analytical Lab and managing the QA Department. Experience leading FDA audits, handling consumer complaints and corrective action programs.

B.S. in Microbiology or Biology required; advanced degree desirable. Must have knowledge of Statistical Process Control Programs; quality design and prevention; validation requirements; manufacturing processes; auditing; ISO certification and auditing; understand the key elements of consumer complaint and corrective action processes. Knowledge of cGMP as it applies to laboratory techniques and systems as well as manufacturing.