

## **Executive Director, Quality Operations**

### **THE COMPANY**

Our client is a leading specialty pharmaceutical company that develops, manufactures, markets and distributes brands and generic pharmaceutical products.

### **LOCATION & COMPENSATION**

This position will be located on Long Island, NY and will report to the Vice President, Quality. It will provide a competitive base salary and appropriate perquisites.

### **POSITION RESPONSIBILITIES**

Functional, organizational responsibility for the site Quality Operations group, including Quality Assurance, Quality Control, and regulatory compliance. Manage and coordinate daily operations of the QA, QC and RC departments, giving proper technical guidance and direction.

Develop and administer the QO budget and align objectives and priorities with those of the rest of the site operations' management team. Has ultimate responsibility for disposition of product manufactured at the site. Assure that the QO group is effective in identifying cGMP deficiencies and that they are properly corrected in a timely fashion. Communicates to Corporate team regarding site compliance and product quality.

Supervise the Quality function to advance current methodology in manufacturing/operational environment. Directly supervise the Quality Systems Manager and the Quality Assurance Department (approximately 53 people.) Ensure quality and integrity of all products and procedures by complying with all internal and governmental requirements.

Give final approval of components, labeling, finished products, operating procedures, work instructions, specifications, analytical test methods, microbiological procedures, validation protocol and results.

Ensure compliance with standards and regulations. Recruit, train, develop and motivate QA personnel. Manage an accurate, reliable, efficient, timely testing function. Establish measures for product and process quality and provide data to management.

Plan QA department work, set and manage objectives. Communicate regulatory, technical and quality information to other departments and personnel as required.

Conduct internal and external customer and regulatory audits. 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 GMP, ISO procedures and work instructions are current and communicated.

## **IDEAL CANDIDATE PROFILE**

Technical expertise in GMP regulations, FDA interaction with pharmaceutical manufacturing operations and industry-wide practice for complying with FDA regulations and expectations.

A seasoned manager with 10 years related quality experience with a regulated food/beverage, healthcare, or consumer products manufacture to include 3-5 years supervising an Analytical Laboratory.

A manager experienced in leading on-site FDA audits, handling customer complaints and corrective action follow-up programs. Knowledgeable in Statistical Process Control programs, quality design and prevention, validation requirements, ISO certification process, auditing procedures and consumer complaints/corrective action processes.

Knowledgeable in GMP as it applies to laboratory techniques and manufacturing processes. Ideal candidate will foster team development and be results oriented with a high energy level and superior communications skills. Candidate will engender respect and confidence among subordinates and superiors.

A driver and culture changer who can bring about process and productivity improvements. Ability to balance and easily alternate between tactical and strategic requirements. An executive with a quality vision and desire and passion to execute it. Leadership/presence – highly disciplined and ability to anticipate and get things done. “Hands on.”

Bachelor's degree in related technical area (e.g., microbiology or biology) and advanced degree is desired. Knowledgeable in water systems, forensic microbiology, and quality inspection/validation processes.