Title: Manager Quality Assurance Systems (CMC/GMP)
Location: Worcester
Reports to (title): Associate Director, Quality Assurance

Overview

The Manager QA Systems is a working supervisor role. They will be responsible for the supervision of up to six (6) direct reports responsible the support of Quality Assurance activities and responsibilities to assure compliance with regulatory and procedural requirements.

Receives assignments in the form of objectives and determines how to use resources to meet schedules and goals. Provides guidance to subordinates within the latitude of established company policies. Recommends changes to policies and establishes procedures that affect immediate organization(s).

Job Complexity

Works on issues of diverse scope where analysis of situation or data requires evaluation of a variety of factors, including an understanding of current business trends. Follows processes and operational policies in selecting methods and techniques for obtaining solutions. Acts as advisor to subordinate(s) to meet schedules and/or resolve technical problems. Develops and administers schedules, performance requirements; may have budget responsibilities. Provides input to Quality Assurance Leadership for headcount and budget.

Specific Responsibilities

This role will specifically mange and oversee traditional Quality Systems (e.g., documentation, change management, supplier management, audit management, etc.) as well as expanding electronic solutions (ZenQMS, etc.). This position requires a high level of organization, creativity, and self-motivation to solve challenges; and offers exposure to a variety of products while contributing to the creation of a quality system. Responsibilities include:

- Identification and reporting of metrics for quality system deliverables. Ensures that systems are in place, functional, and conforming to internal procedures and external guidance.
- Overseeing the team that provides end user support for the use and access of the electronic solution.
- Working with Quality Assurance Training personnel to develop / maintain curricula for training and system access requirements. Coordinates the configuration, upgrade, and maintenance of electronic solution.
- Participating in project work and initiatives associated with Quality System issues in conformance to regulatory requirements. Interfaces and provides Compliance guidance/support to Operations
- Providing input to Quality Assurance Leadership for headcount and budget.
- Working with leadership to identify, manage, and develop direct reports.
- Directly supporting audit by regulatory authorities or other outside parties as required.

About You

Education: Bachelor's degree in Chemistry, Biological Sciences, Computer Science or related field, or equivalent combination of education and work experience.

Qualifications and Experience:

- 5+ years in a Quality Assurance, Quality Systems, or Quality Control Role in the pharmaceutical, biotech, or medical device industry dealing with quality
- Knowledge of GMP regulations and quality systems
- Prior experience effectively managing a high performing team
- Excellent attention to detail, organizational skills, and ability to multi-task in a dynamic environment

Skills and Abilities:

- Frequently interacts with subordinate supervisors, customers, and/or functional peer group managers, normally involving matters between functional areas, other company divisions or units, or customers and the company
- Ability to lead a cooperative effort among members of a project team
- Effective interviewing and solicitation skills in individual and group settings
- Ability to work independently based on set expectations
- Ability to identify opportunities for process improvements and communicate appropriately
- Ability to problem-solve independently
- Strong and effective organizational skills
- Ability to motivate others who have other reporting structures

Please submit resume and cover letter to careers@mustangbio.com.