

POSTION DESCRIPTION:

Director, Quality requires strong GLP/FDA experience within the Life Sciences industries (such as Biotechnology and Contract Research) - this is NOT a position within the scope of IT, Manufacturing, or Food. Please carefully review the description of the duties/qualifications before applying.

General Summary

Based in the Birmingham, AL office, this position is responsible for leading and managing the Quality function for Southern Research Institute, which includes maintaining and ensuring compliance within the quality assurance, validation, and document management programs. Plans and coordinates the activities necessary to provide management with confidence that the Institute's products and services satisfy quality and regulatory requirements and for reporting the status of such compliance to management on a periodic basis.

Key Responsibilities:

- Ensure that all systems are in place to facilitate GLP compliance (as defined by the FDA) at multiple sites: Frederick, MD and Birmingham, AL.
- Directs the Institute's Quality personnel, including the establishment of goals, schedules, priorities, staffing, training, and budgets.
- Develops quality operating policies and procedures that affect subordinate organizational units.
- Reviews Quality system and methods on a periodic basis to ensure its efficient operation and its compliance with applicable regulations and standards.
- Reviews and disseminates regulatory reference information that may affect the operation of the Quality unit or other areas.

Position Specific:

- Reports the status of compliance with applicable regulations and standards that relate to studies, operations, and facilities to management.
- Reviews inspection reports to assess findings, responses, and need for follow-up activities.
- Ensures that the Good Laboratory Practice Master Schedule is maintained according to regulations, standards, and procedures.
- Serves as a key contact for regulatory inspections and provides input for responses to those regulatory inspections.
- Provides project costing estimates and quality assurance unit input for proposals.

- Serves as an internal consultant for system validation projects.
- Performs audits of subcontractors who provide support for regulated work.
- Effectively communicates with Institute personnel, clients, subcontractors, regulatory inspectors, and third party organizations.
- Hires, reviews, motivates, and disciplines, as appropriate, quality assurance unit personnel.
- Ensures that budgets are realistically established and attained.
- Other duties as required by organization management.

Requirements/Minimum Qualifications:

- Bachelor's degree in relevant discipline
- 10+ years of experience with regulations and standards (i.e., Good Laboratory Practices)
- Strong background/experience implementing GLP
- Proven ability to develop training and quality systems
- Ability to lead, motivate and manage staff performance
- Ability to successfully implement business processes
- Ability to observe appropriate safety and study requirements by reading, understanding and following Standard Operating Procedures (SOP), Good Laboratory Practice (GLP) requirements and study protocols.
- Certification as a GLP Professional (e.g. RQAP-GLP) is required.
- Must be able to receive all necessary vaccines to enter the BSL-3 and must not be a "restricted person" under the requirements necessary for Possession, Use and Transfer of Select Agents and Toxins.
- Must be able to pass the medical surveillance physical and obtain select agent clearance through CDC and the FBI.

Core Behaviors

Customer Focus: Makes customers and their needs a primary focus of one's actions; developing and sustaining productive customer relations.

Contributes to Team Success: Actively participates as a member of a team to move the team toward the completion of goals.

Builds Trust: Interacting with others in a way that gives them confidence in one's intentions and those of the organization.

Results Achievement: Takes prompt action to accomplish objectives; takes action to achieve goals beyond what is required; is proactive.

Safety Awareness: Identifies and corrects conditions that affect employee safety; upholds safety standards.

To Apply:

<http://careers.peoplecapital.com/sricareers/apply.asp>