

## Director, Quality Assurance

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**KCAS Bioanalytical & Biomarker Services** is seeking a Director of Quality Assurance (QA) to manage a QA department within a growing organization in the greater Kansas City area located in Shawnee, Kansas. KCAS is a contract research organization (CRO) providing bioanalytical & biomarker services to pharmaceutical clients in support of drug developments, preclinical and clinical studies.

This job ad is meant to provide a brief overview of the nature and level of work being performed and does not imply that these are the only duties to be performed.

### **Position Summary:**

The Director of QA manages one or more QA departments/groups that are staffed by professional employees performing quality assurance functions. Interacts, with executive management, clients and regulatory agencies as needed regarding quality systems, audits and inspections. Maintains a high level of professional expertise and leads regulatory inspections during FDA and critical client audits. Responsible for meeting department goals and objectives. Serves as a member of the Senior Leadership Team.

### **Key Job Responsibilities:**

Typical responsibilities of Director of QA may include, but are not limited to, the following:

- Assure Quality systems are designed and performing to meet industry, regulatory and executive management requirements.
- Initiate employee hire, promotion, discharge, or transfer.
- Participate in the selection process for subordinate personnel including determining recruiting criteria, interviewing, and performing reference checks.
- Perform annual performance evaluations for direct reports.
- Require and monitor training for subordinates to develop them to their potential.
- Effectively use delegation to develop subordinates.
- Perform career planning for subordinates.
- Provide encouragement and positive reinforcement to subordinates; require subordinate management staff to do the same.
- Participate in the development of short and long-range goals and objectives, implement and attain short and long-range goals and objectives, and assure that year-end goals are attained.
- Assure that all departmental management staff are working in concert with each other.
- Coordinate activities of the department with related activities of other departments, to ensure efficiency and economy.
- Understand, communicate and cascade communication from Executive management.
- Be knowledgeable of departmental budget and will monitor and analyze cost against budget.

## Director, Quality Assurance

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- Overall responsibility for the Quality Assurance operation, compliance and department goals including budget management.
- Interact with clients relating to quality audits and responses to study data, and to understand client needs/expectations.
- Forecast and recommend strategies to accommodate growth when needed (space, equipment, human resource).
- Establish policies and procedures to ensure that the Quality operations maintains a high level of quality expertise, remains abreast of current technologies and comply with related regulatory policies, OSHA and company SOPs/policies.
- Audit reports, data, internal processes and procedures to support management to improve data integrity, reduce error rates and efficiency.
- Ensure appropriate validation of methodology and instrumentation per regulatory requirement/industry expectation.
- Review/update SOPs to reflect current practice and regulatory requirements.
- Maintain expert knowledge of bioanalytical scientific trends as well as regulatory requirements.
- Perform complex quality assignments with understanding of underlying scientific principles.
- Recommend and institute, systems and programs to improve safety, work quality, cost saving and productivity.
- Effectively interface with various functional units, groups or departments in the company.

### Education and Experience:

- Bachelor's degree in a related field.
- 10 years industry related experience, including 2 years supervisory experience.
- Broad knowledge of regulatory requirements applicable to areas managed.
- Extensive knowledge of processes applicable to subordinate groups.
- Awareness of industry trends related to areas managed.
- Computer proficiency.
- Perform all aspects of job in a way that supports company brand and company mission, vision and values.

### Competencies, Skills & Personal Attributes:

- Problem solving.
- Consistent attention to details.
- Leadership skills.
- Time management skill.
- Organizational skills.

## Director, Quality Assurance

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- Presentation skills.
- Multitasking abilities.

### **Physical Requirements:**

- Ability to lift 20 pounds.
- Ability to sit or stand for extended periods of time.
- Ability to convey complex information clearly and concisely.
- Ability to ascend and descend stairs.

*KCAS is proud to be an Equal Opportunity employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, national origin, ancestry, marital status, veteran status, age, disability, pregnancy, genetic information, sex, sexual orientation, gender identity or any other legally protected category.*