



Bioanalytical & Biomarker Services

## Quality Assurance Manager

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**KCAS Bioanalytical & Biomarker Services** is seeking a Quality Assurance (QA) Manager to assist with a variety of processes within the QA department of a growing organization 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 QA Manager manages QA team(s). Interacts with clients and regulatory agencies as needed regarding quality issues, audits, and inspections. Performs activities of highest variety and complexity to ensure quality and compliance with applicable regulatory requirements, including document review, audits, inspections, consulting on quality and compliance issues, training, and trend analysis. Uses a high level of expertise to provide mentoring and direction to team members.

### **Key Job Responsibilities:**

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

- Perform management duties for subordinates, including but not limited to, assisting in recruiting efforts, development and attainment of goals, annual reviews, training and development, delegation and time-card approval and requests.
- Work in concert with departmental management and leadership.
- Understand, communicate and cascade communication from the department's Director.
- Be knowledgeable of departmental budget and will execute performance to meet budget.
- Performs quality review and approval of documents, data, protocols, and/or reports.
- Reviews laboratory deviations and investigations.
- Maintains accurate quality assurance files, records, and databases, and may perform analysis and trending.
- Provides consultation on quality and compliance topics in areas of expertise as well as quality improvement initiatives as needed.
- Provides training in complex quality and compliance topics.
- Development and write quality SOPs, documents and/or reports as needed.
- Serves as client quality liaison and/or quality host of client audits; coordinates responses to client audits.
- Domestic and international travel may occasionally be required.

### **Education and Experience:**

- Bachelor's degree.
  - 6 years industry related experience.
  - Broad knowledge of regulatory requirements, applicable to areas managed.
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- Extensive knowledge of processes applicable to subordinate employees.
- Awareness of industry trends related to areas managed.
- Computer proficiency.
- Previous management experience.

### **Competencies, Skills & Personal Attributes:**

- Problem solving skills and abilities.
- Consistent attention to details.
- Leadership skills.
- Time management skills.
- Organizational skills
- Presentation skills.
- Multitasking abilities.
- Perform all aspects of job in a way that supports company brand and supports company mission, vision and values.

### **Physical Requirements:**

- Ability to lift 20 pounds.
- Ability to sit or stand for extended periods of time.
- Ability to ascend and descend stairs.