

## Quality Specialist III

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**KCAS Bioanalytical & Biomarker Services** is seeking a Quality Specialist III to assist with a variety of tasks 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 Quality Specialist III performs activities of moderate 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.

### **Key Job Responsibilities:**

Typical responsibilities of Quality Specialist III may include, but are not limited to, the following:

- Performs quality review and approval of documents, data, protocols, and/or reports.
- Performs quality audits and/or inspections, preparing and distributing audit reports to study director, principal investigator, and/or management in a timely manner.
- 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 and assists with quality improvement initiatives as needed.
- Provide training in routine and moderately complex quality and compliance topics.
- Assists with development/writing of quality SOPs, documents and/or reports as needed.
- Serve as client quality liaison and/or quality host of client audits; coordinates responses to client audits.
- Serve as a mentor to less experienced associates.

### **Education and Experience:**

- High School Diploma required, Bachelor's degree preferred.
- 3 years of relevant QA experience.
- Detailed knowledge of and familiarity with laboratory procedures, processes, and common issues.
- Extensive understanding of governmental regulations.
- Familiarity with quality assurance best practices and emerging trends.

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### Competencies, Skills & Personal Attributes:

- Excellent written and verbal communication skills.
- Good basic math skills.
- Good computer skills.
- Strong analytical skills and attention to detail.
- Strong interpersonal and customer relations skills
- Ability and willingness to mentor others.
- 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 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.*