



Bioanalytical & Biomarker Services

Quality Specialist II

KCAS Bioanalytical & Biomarker Services is seeking a Quality Specialist II 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:

Performs activities of some variety and complexity to ensure quality and compliance with applicable regulatory requirements, including document review, audits, inspections, and consulting on quality and compliance issues.

Key Job Responsibilities:

Typical responsibilities of Quality Specialist II 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.
- Provide training assistance in routine quality and compliance topics.
- Assists with development/writing of quality SOPs, documents and/or reports as needed.
- Provides consultation on quality and compliance topics in areas of expertise and assists with quality improvement initiatives as needed.

Education and Experience:

- High School Diploma required, Bachelor's degree preferred.
- 1 year of relevant QA experience.
- Basic familiarity with governmental regulations.
- Exposure to and basic awareness of laboratory processes.

Competencies, Skills & Personal Attributes:

- Good written and verbal communication skills
 - Good basic math skills
 - Good computer skills
 - Strong analytical skills and attention to detail.
 - Perform all aspects of job in a way that supports company brand and supports company mission, vision and values.
-

Quality Specialist II

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.