Triclinic Labs
Solid-State Expertise for Discovering, Developing, and Protecting Pharmaceutical Intellectual Property

Job Description
QA Specialist
Triclinic Labs, Inc.

Position Summary:

This position contributes to the success of the organization by providing oversight into regulatory aspects of the business.

Primary responsibilities include:

- Review and approve deviations, corrective and preventative actions and change controls
- Participate in client audits and regulatory inspections
- Ensure quality systems comply with company procedures and regulatory expectations,
- Train staff and key personnel in company procedures and current industry expectations
- Support product validations and designs
- Audit scientific reports
- Conduct internal audits
- Evaluate the impact of any new product or changes to existing products on regulatory applications
- Able to apply standard operating procedures to daily activities
- Performs other duties as assigned

Skills:

- Excellent written and verbal communications skills
- Ability to motivate peers
- Excellent computer skills
- Able to work on pressure
- Ability to multi-task
- Collaborate with other members of a project team to accomplish team objectives.
- Ability to generalize experimental design.
- Ability to clearly communicate ideas, research results, and conclusions.
- Familiarity and exposure to cGMP or other regulatory requirements.

Required Qualifications:

- Bachelor's or Master's degree, preferably in a science field or equivalent regulatory experience.
- Preference given to those individuals with cGMP experience

Physical Requirements:

- Must be able to adjust and/or lift up to 30 lbs. infrequently
- Must be able to go from sitting to standing or vice versa for extended periods in an office and laboratory environment. This also includes walking to and from various instruments/locations throughout the lab.
- Must be able to work in laboratory testing.
- Must be able to work in a medium to high noise level.