

## **Quality Assurance Specialist**

**Alliance Pharma, Inc.** is a contract research organization (CRO) located in Malvern, PA specializing in advanced bioanalytical and drug metabolism services.

Alliance is looking for an experienced Quality Assurance (QA) Auditor. In this position you will perform protocol/sample analysis plan, data, report, and study phase inspections to verify conformance to applicable SOP, method and regulatory requirements.

### **Responsibilities:**

- Manage all aspects of audit assignments independently, with minimal supervision
- Assist with SOP reviews
- Participate in internal facility and process inspections
- Participate as needed in client and regulatory inspections as part of the QA team
- Actively participate in process improvement efforts
- Deliver basic quality/regulatory training

### **Education/Qualifications:**

- Minimum Bachelor's degree (BS/BA) in a science field (e.g. biology, chemistry)
- Ability to work with basic computer programs (Word, Excel, Powerpoint, etc.)
- Advanced knowledge of FDA regulations (GLP, GCP), EPA GLPs a plus
- Knowledge of the drug development process
- Knowledge of scientific terminology, especially related to bioanalysis
- Advanced knowledge of regulatory guidance related to bioanalysis
- Must be detail oriented and organized
- Must have excellent written, communication and presentation skills
- Successful candidate must be a team player

### **Experience:**

- Minimum of 4 years of experience as a QA auditor in a fast-paced CRO environment
- Experience with computer systems validation auditing a plus

*For more information or to submit your resume please contact:*

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