

## **QC Supervisor**

Applied Genetic Technologies Corporation (AGTC) is a clinical stage biotechnology company dedicated to developing novel gene therapies for ophthalmic diseases. The QC Supervisor has the responsibility of establishing and supervising quality control systems and activities. The key responsibilities are to ensure that products conform to quality standards and governmental regulations. The successful candidate will be instrumental in the startup of an in-house QC laboratory.

### **Reporting Relationship**

- The QC Supervisor will report directly to the Director, Quality Assurance.

### **Responsibilities**

Job responsibilities will include, but not limited to the following:

- Develop product quality control program for late stage clinical development
- Develop and manage QC analytical training program
- Supervise and monitor internal and external QC analytical testing up to and including review of sampling plans, test data and related documents for in-process testing, drug substance and drug product release
- Generate CoAs for product release
- Develop and manage stability program. Design and generate protocols for stability studies, write final reports, procure inventory and supplies. Monitor and trend data
- Develop, revise and review SOPs, analytical test methods, instrument validation protocols and reports
- Establish specification and testing processes for raw materials
- Conduct investigations regarding out-of-specification (OOS) results, trends in invalid assay and address and manage deviations related to QC analytical procedures
- Support the transfer of analytical methods from the Analytical Development group to QC and external vendors

### **Requirements**

The successful candidate will meet the following requirements:

- A minimum of a BS degree in a scientific discipline with a minimum of 5-7 years of related experience in quality control is required
- Must have significant working knowledge, competency and experience in cGMP environments. Working experience with GLP regulations is a plus
- Well versed in various analytical techniques such as HPLC, Mass Spectrometry, DNA quantification, ELISA, qPCR, cell-based assays and other methods applicable to the testing of biologics
- Comfortable in a fast-paced small company environment with minimal direction and able to adjust workload based on changing priorities
- Excellent interpersonal, verbal and written communication skills

AGTC offers a competitive compensation commensurate with education and experience, including salary, benefits, and company equity. AGTC is an EOE and maintains a drug free workplace. Please submit CV or resume to: [Jobs@AGTC.com](mailto:Jobs@AGTC.com)