Visionary science for life changing cures.

Clinical QA Specialist

Applied Genetic Technologies Corporation (AGTC) is a clinical stage biotechnology company dedicated to developing novel gene therapies for ophthalmic diseases. The Clinical Quality Assurance (QA) Specialist provides Quality oversight of internal and external clinical trial activities, related records and processes to assure management in accordance with FDA regulations, ICH-GCP, SOPs, and all other applicable regulations and assists with tasks necessary to achieve department and/or company goals.

Reporting Relationship

- The Clinical Quality Assurance Specialist will report directly to the Director, Quality Assurance.

Essential Duties and Responsibilities

- Identify and address GCP compliance issues across AGTC clinical systems and processes to strengthen their Quality and ensure a state of readiness for regulatory inspection
- Contribute in the development of Clinical Operations, Safety and Clinical Quality and Compliance systems and standards
- Plan, track and oversee GCP and GCLP audits of CROs and contract laboratories to assure compliance with internal procedures and regulatory guidelines
- Assist in resolving compliance issues at clinical sites, clinical vendors, and laboratories; and provide assessment of the impact of any deficiencies
- Assist with ICH/GCP Training at investigator meetings and internally
- Develop and measure GCP quality metrics to drive consistent quality standards throughout the organization
- Maintain relevant knowledge of appropriate GxP requirements and developments as they impact company SOPs and compliance with GxP, and communicate these to the QA team and QA management, as applicable

Educational Qualifications

- A BA or BS degree in a scientific discipline and 3 to 5 years' experience in a GCP environment, with at least 3 years working in a QA role supporting GCP compliance.

Additional Experience

- Proficient knowledge of ICH, GCP, and applicable CFRs, guidance documents, systems processes and procedures
- Excellent interpersonal, verbal and written communication skills to build good working relationships both internally and externally
- Experience in clinical operations and handling trial essential documents is preferred.
- Additional experience conducting GLP and/or GMP audits a plus

AGTC offers competitive compensation commensurate with education and experience. AGTC is an EOE and maintains a drug-free workplace. Please send CV or resume to: jobs@agtc.com