



*Visionary science for
life changing cures.*

Research Associate II, Assay Development

The Research Associate II, Assay Development will be responsible developing new and validating established assays for use in GLP and GMP environments for the characterization of AAV and HSV vectors. He/she will assist in all development and validation activities of assays and serve as a subject matter expert for their transfer and troubleshooting at CTOs and AGTC partners.

Responsibilities:

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

- Develop assay methods for viral-based gene therapeutic testing to support IND enabling non-clinical animal study material characterization and human clinical material release
- Validate established assays for use in viral vector raw material characterization, process definition, late phase clinical material release and/or commercialization activities
- Troubleshoot, optimize and refine assays for increased sensitivity, robustness, linearity and specificity
- Participate in assay transfer activities, including contract vendor interactions, assay transfer, troubleshooting and oversight
- Collect, analyze, record, and summarize data
- Write and/or review SOPs, technical reports and study reports
- Maintain relevant laboratory supplies and equipment as needed
- Present scientific results at appropriate meetings
- Knowledge of laboratory safety, OSHA policies, and EPA standards
- Compliance with FDA regulations regarding GXP standards

Requirements:

The successful candidate will meet the following requirements:

- A B.S. with 5 + years of experience or an M.S. with 3 + years of experience with a degree in a biological science and at least 2 years of industrial experience in assay development
- Hands-on laboratory experience with in vitro assays encompassing immunology, molecular biology and/or cell biology such as ELISAs, PCR, and mammalian cell-based assays
- Ability to develop new assay methods to ICH requirements with minimal supervision
- Previous assay validation experience and knowledge of statistics is highly desirable
- Highly motivated with the ability to work independently and in a team
- Detail oriented with strong written and verbal communication skills in English
- Understanding/working knowledge of Microsoft Word, Excel and PowerPoint

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 send CV or resume to:

Human Resources
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