



Job Description – Analytical Development Associate Scientist/Scientist

Avenge is looking for a highly motivated analytical development scientist who is eager to join a growing organization that aims to treat solid tumors with a cell-based immunotherapy. This person will focus on analytical assay characterization and support assay development and tech transfer. This role will also provide person-in-plant support during clinical manufacturing and testing activities with Contract Manufacturing Organizations (CMOs). They should be detail oriented and have strong understanding and technical knowledge of analytical assay development, including ELISA's, bioassays, cell characterization assays, etc. Additionally, this person will play a major role supporting process development and routine internal testing. This person should have experience and will participate in generating and updating SOPs, testing forms, and other GMP documents.

Responsibilities:

- Characterize and evaluate current analytical assays, identify improvement opportunities and perform experiments to generate beneficial changes to current methods.
- Provide oversight for GMP testing activities and assist in troubleshooting analytical issues as they arise.
- Assist in on-going process development work by providing analytical testing support in the lab.
- Develop new analytical assays required for late-phase manufacturing and pipeline programs. Support method transfer and method qualification at the external testing labs.
- Support execution of development stability studies.
- Support technology transfer and clinical QC testing activities for a cell therapy product with Contract Manufacturing Organizations (CMOs) and/or CTLs (Contract Testing Labs)
- Work with QA to facilitate resolution of CMO/CTL quality issues (e.g. OOSs, investigations, CAPAs, etc.).
- Apply relevant scientific literature and maintain an understanding of current trends and emerging technologies associated with technical function.
- Author SOP's and other GMP documentation to support and implement analytical changes. Author and update internal SOPs to ensure alignment between internal and external data generation.
- Assist with lab scheduling and coordination of activities. Support lab functions-including, but not limited to restocking consumables, maintaining equipment, and cleaning.
- Make detailed observations, maintain a laboratory notebook, ensure ELN pages are up-to-date and accurate.
- Serve as person-in-plant for clinical manufacturing runs, as needed.
- Reports to the Associate Director of Analytical Development at Avenge Bio.

Preferred Qualifications:

- BS or MS degree in life sciences, biology, chemical, materials, or mechanical engineering or relevant field



- Advanced understanding of analytical methods that support both drug substance and drug product testing.
- Direct experience working with CTLs (Contract Testing Labs) or CMOs and supporting tech transfer and/or GMP clinical manufacturing operations.
- Attention to detail, critical analysis of data, and troubleshooting abilities
- Ability in prioritization of experiments, data analysis, and lab operations
- Highly collaborative working style, and ability to adapt in a fast-paced environment
- Experience in GMP/GDP quality control testing
- Experience in culturing different mammalian cell lines and associated aseptic techniques is a plus
- Knowledge of microbiological assays (endotoxin, sterility, mycoplasma) is a plus.
- Previous experience (5-8 years with a BS or 4-5 years with an MS) in biotech/pharma or cell and gene therapy.

About Avenge Bio:

Avenge Bio, Inc. (“Avenge”) is an oncology-focused biotechnology company developing transformative cell-based immunotherapeutic products for the treatment of intractable solid tumors by incorporating its LOCOcyte™ platform. The LOCOcyte™ platform leverages proprietary engineered cells delivered to the local tumor environment that generate high concentrations of immune effector molecules in proximity to the tumor. This initiates a robust, local and durable systemic immune response while avoiding toxicities associated with systemic immunotherapies. Avenge's most advanced product candidate, AVB-001, produces native IL-2 immunotherapy and is initially being studied in metastatic peritoneal cancers such as ovarian cancer. Avenge has additional pipeline candidates for the treatment of a wide range of cancers including pancreatic, lung and breast cancers. Avenge Bio was founded in 2019 based upon technology developed in the laboratory of Omid Veischi, Ph.D. and has an exclusive license from Rice University for this technology. To learn more, visit www.avengebio.com.