

Job Description – Process Development Scientist (I, II, III)

Responsibilities

- Technical lead for drug substance and drug product formulation, storage, and stability to support of product development from clinical to commercial scale
- Design, perform, and manage experiments associated with prolonging stability to assess changes in the process to drive company decisions
- Collaborate with other scientists to establish critical process parameters for drug substance and drug product
- Analyze and evaluate current manufacturing processes, equipment, and materials to present trends and make recommendations using statistical analysis, program objectives, and capital justifications
- Apply relevant scientific literature and maintain an understanding of current trends and emerging technologies associate with technical function
- Author technical reports and risk assessments to support regulatory filings.
- Manage external development work and tech transfer
- Make detailed observations and maintain a laboratory notebook
- Mentor and/or manage research associates
- Contribute to the development of the team and strategy for the preservation and storage of drug substance and drug product
- Reports to the Director of Process Engineering at Avenge Bio

Preferred Qualifications

- BS (5-8 years), MS (2-4 years), or PhD (0-3 years) degree in biological, chemical, materials, or mechanical engineering or relevant field
- Attention to detail, critical analysis of data, and troubleshooting abilities
- Highly collaborative working style, and ability to adapt in a fast-paced environment
- Experience with analytical methods that support both drug substance and drug product stability testing.
- Experience in culturing different mammalian cell lines and aseptic techniques
- Ability in prioritization experiments, data analysis, and lab operations
- Exposure to cryopreservation techniques, biomaterials, and cell encapsulation is a plus
- Understanding of guidelines for stability testing for cell therapy products is a plus
- Previous experience (1-3+ years) in biotech/pharma or cell and gene therapy is a plus

About Avenge Bio:

Avenge Bio, Inc. 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 Veisheh, Ph.D. and has an exclusive license from Rice University for this technology. To learn more, visit www.avengebio.com

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