AVENGE BIO

Job Description – Manager, Quality Assurance

Avenge is looking for highly motivated candidates who are eager to join a growing organization that aims to treat solid tumors with a cell-based immunotherapy. This person will focus on quality operations with respect to day-to-day clinical manufacturing activities with Contract Manufacturing Organizations (CMOs) and their testing at Contract Testing Labs (CTLs). They should be detail oriented and have strong understanding and technical knowledge of GMP, GCP, GLP processes, data integrity and compliance. Additionally, this person will play a major role in reviewing SOPs and GMP manufacturing batch records to ensure timely delivery of clinical supply. This person should have experience and will participate on manufacturing deviations, investigations, CAPA, and Change Controls and work closely with the quality organization.

Responsibilities:

- Document Control responsibilities for issuing, maintaining, controlling, and revising documents in eQMS.
- Assisting and working with cross functional teams to develop and establish templates, proofread and create new document requirements.
- Oversee training records, update training matrix and prepare training reports.
- Review and manage executed batch records for drug substance and drug product materials prepared at CDMO to release product.
- Assist with thorough verification of materials used, GDP and quality issues on executed batch records.
- Participate and manage deviations and CAPA's related to drug substance and drug product preparation
- Archive batch related information including COA’s etc. in eQMS
- Participate and assist with change controls and change requests to manage updates.
- Support building a strong quality culture and provide adequate training on quality systems for research and development teams.
- Reports to the Director of Quality Operations at Avenge Bio.

Preferred Qualifications

- BS (5-8 years) or MS (3-5 years) with direct experience in quality assurance
- Direct experience in quality assurance across product development lifecycle and batch release functions
- Written communication skills and experience with QMS software and electronic applications
- Experience with FDA and cGMP quality systems and guidance
- Highly collaborative working style, and ability to adapt in a fast-paced environment
- Meticulous attention to detail and well-organized

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 systemic durable immune response while avoiding toxicities associated with systemic immunotherapies. Avenge's most advanced product candidate, AVB-001, produces native IL-2 and is initially being studied as an immunotherapy 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 was founded in 2019 after in-licensing the exclusive license for the LOCOcyte technology from Rice University. Since inception, Avenge has raised equity capital from top tier investors including Longitude Capital, Blackstone (CAM Capital), Perceptive Xontogeny Venture Fund, Rock Springs Capital, and Pappas Capital. To learn more about Avenge visit www.avengebio.com.