

Job Description – Director, External Manufacturing & Supply Chain

Avenge is looking for a highly motivated Director of External Manufacturing & Supply Chain who is eager to join a growing organization that aims to treat solid tumors with a cell-based immunotherapy. This person will serve as a primary point of contact for Avenge’s external Contract Manufacturing Organization (CMO) network including raw material suppliers. He/she will lead due diligence activities for selection of CMOs and Contract Testing Labs (CTLs) and lead capacity planning for clinical/commercial manufacturing. He/She will contribute to overall CMC strategy development and partner with project team members to align manufacturing plans with overall project plans. He/She will also serve as a Supply Chain lead to ensure successful distribution of clinical trial material to clinical sites. He/She will work closely with Clinical Operations team to plan and manage clinical drug product inventory, label design, packaging, logistics and shipping of finished drug product.

Responsibilities:

- Serve as a primary point of contact and relationship manager to CMOs/CTLs and critical raw material suppliers (domestic and international).
- Areas of focus will include supplier management, project management, production planning, logistics, and shipping.
- Responsible for developing manufacturing service and supply agreements in close collaboration with Legal, Finance, and Quality
- Lead contract setup and negotiation, budget planning, tracking, contracts, and RFP (request for proposal) processes.
- Develop planning methodology and inventory policy for critical materials, ensuring material supply meets internal and external projects.
- Serve as the Supply Chain lead on matrix teams for complex projects and establish and maintain detailed project plans.
- Align external manufacturing schedules and forecast requirements. Proactively define risks and recommend contingency plans.
- Identify and escalate business critical risks impacting supply and/or timelines with related mitigations and/or possible solutions.
- Monitor CMO performance using a set of standard KPIs and report progress to management.
- Manage shipping vendors and ensure successful delivery of cell therapy drug products to clinical sites.

Qualifications:

- BS/MS in Biology, Chemistry, Chemical/Biochemical/Biomedical Engineering with 10+ years of experience or PhD in similar field with 7+ years of experience.
- A strong understanding of product development and GMP Manufacturing is required.
- Direct experience in managing CMOs is required.
- Working knowledge of regulations relating to pharmaceutical supply chain activities (cGMP, GCP, import/export, computer systems/Part 11).



- Expertise in a supply chain discipline (e.g., production planning, clinical supplies, logistics, ERP/MPR systems administration)
- A strategic thinker with strong result-orientation and a sense of urgency to deliver quality results on time and in a highly ethical and professional manner.
- Excellent communication and interpersonal skills with the ability to build strong cross-functional relationships and communicate complex issues and concepts.
- Problem solver with a hands-on approach and ability to anticipate adverse scenarios and provide contingency plans to address.
- Ability to travel up to 20%

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