Job Code CBA-PW-11

About GenScript

GenScript Biotech is the world leader in the biotechnology reagent service industry, as well as an open platform for pre-clinical drugs discovery and pharmaceutical development, driven by innovative technologies. As a public company (HK Stock: 01548), our mission is to make human and nature healthier through biotechnology. Established in 2002, the company headquarter is located in Nanjing, China, with production and operation center in both Nanjing and New Jersey, United States. There are also branches in EU, an R&D center in Ireland and a logistics center in Netherland, and branch in Japan. With these facilities, we have been serving more than 100 countries and 200,000+ customers around the world for more than 16 years. For more details, please refer to our website www.genscript.com.

Position Information	
Position Title:	Manufacturing Manager
Work Location:	Central NJ
Employment Status:	Full-time permanent
Reports to:	Vice President, GMP Site Head
Direct Reports (#/level):	TBD
Language:	English

Position Overview

The position reports directly to the Site Head, is ideal for a professional with excellent technical knowledge and great passion of developing leadership and management skills suitable for manufacturing of a wide range of clinical or commercial materials, for cell and gene therapy drugs. This is a great opportunity to evolve the function within a CDMO business, to support a broad portfolio and advance the manufacturing capabilities to deliver products to the client projects that transform the lives of patients.

1. As the manufacturing leader, responsible for making GMP batches following plasmid DNA or viral vector products manufacturing process flows; delivering high quality products to clients' projects, ensuring full compliance of SOPs and policies.
2. Recruit and build a high-performing manufacturing team, ensure operators' safety, quality and on-the-job trainings.
3. Manage daily manufacturing schedule, conduct necessary coordination and communications with EHS, warehouse, QA, QC and facility engineering. Generate or suggest high-efficiency workflows with different functional groups. Able to adapt changes when necessary.
4. Owner of manufacturing suites and process equipment. Work with facility engineering and quality teams to ensure a functional GMP environment for CDMO needs.
5. Monitor batch-to-batch manufacturing activities, conduct risk assessment, identify potential compliance/quality gaps, work with quality team for resolutions, and implement corrective actions.
6. Present updates to project or upper management teams on manufacturing activities.

7. Maintain a high level of knowledge in gene and cell therapy, sensitive in the field of T cell (CAR-T, TCR) and other novel product development and manufacturing.
8. Perform other duties as assigned based on business needs.

Qualifications

1. Bachelor's degree in Pharmaceutical Chemistry, Chemical Engineering, Biology, Molecular Biology, Biochemistry, Biomolecular Engineering or equivalent, 5-7 years in biotech manufacturing with particular experience in gene and cell therapy production GMP environment. Experience with plasmid DNA, recombinant viral vectors, mRNA or gene modified T cell products is a plus.
2. Technical knowledge and hands-on experience in process development or "Scale-up" of immune cell therapy technologies, gene editing and gene therapy technologies.
3. Experience in GMP-scale production with clinical or commercial manufacturing requirements, familiar with fermentation and purification equipment and systems. Experience in single-use 10L-300L bioreactor/fermenter is a plus.
4. Direct management experience with successful track record of building, coaching and mentoring a high-performing team, executing daily tasks to complete and deliver manufacturing batches.
5. Understand essentials and requirements of quality management systems (QMS) used in GMP productions. Ability to collaborate with all internal and external function groups, and adapt the priority and timeline change.
6. Experience in CMC regulatory affairs for FDA, and EMA is a plus.
7. Strong interpersonal, verbal, and written communication skills.

Job title is subject to change based on candidate experience.

GenScript USA Inc. is a proud equal opportunity/affirmative action employer committed to attracting, retaining, and maximizing the performance of a diverse and inclusive workforce. It is GenScript's policy to ensure equal employment opportunity without discrimination or harassment based on race, color, religion, sex (including pregnancy, childbirth, or related medical conditions), sexual orientation, gender identity or expression, age, disability, national origin, marital or domestic/civil partnership status, genetic information, citizenship status, uniformed service member or veteran status, or any other characteristic protected by law.

GenScript USA Inc. maintains a drug-free workplace.

Please send inquiry with Job Code identity to:
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