Job Code CBA-PW-12

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:	MSAT Engineer
Work Location:	Central NJ
Employment Status:	Full-time permanent
Reports to:	Vice President, GMP Site Head
Direct Reports (#/level):	N/A
Language:	English

Position Overview

The position reports to the US site head, is ideally suited for a professional with good process and engineering knowledge, suitable in GMP manufacturing of a wide range of clinical trial materials. This is a great opportunity to lead and evolve this 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. This role will focus on aspects of ensuring a robust, scalable and efficient manufacturing process to produce late-phase human clinical trial and commercial gene transfer biological products.

Key Responsibilities:

1. Lead cross-functional technology transfer activities for cGMP manufacturing processes.
2. Collaborate with another site or clients to ensure success of scale up/process transfer.
3. Lead process-related deviations and provide technical support to manufacturing.
4. Investigate, identify root-cause for critical deviations and determine CAPA for manufacturing.
5. Write and review technical documentation (SOPs, protocols, and reports).
6. Ensure successful manufacturing production runs by assessing risk, setting preventative measures in place, investigating, and troubleshooting equipment and process issues.
7. Design and execute process validation studies to develop a thorough understanding of operating and performance parameters.

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8. Perform hands-on activities that support process development and process characterization, ranging from drafting procedures to execution of laboratory studies.
9. Train operations staff on process workflow and process characterizations. Use appropriate manufacturing execution/quality systems. Peer review or approval of related process development and manufacturing documents.

Qualifications

1. Bachelor or advanced degree in Biochemical, BioMolecular, Chemical Engineering or a related scientific discipline such as Chemistry or Biology.
2. 5+ years relevant experience or Master's degree with 3+ years relevant experience.
3. cGMP pharmaceutical MSAT or technical services, technology transfer or process development experience preferred.
4. Strong interpersonal and communications skills, written and verbal.
5. Ability to function in a fast-paced dynamic team environment and balance characterization multiple projects
6. Knowledge of cell and gene therapy vector production is desirable.
7. Understands and employs principles and concepts of Lean Six Sigma to improve process capability is a plus.
8. Knowledge of data management tools and statistical process controls is preferred.

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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