

Engineer, Manufacturing Science and Tech

Job ID
REQ-10022820

9月 18, 2024

USA

摘要

The Engineer, Manufacturing Science and Technology assists with the development and improvement activities for the cell culture, recovery, purification, and/or aseptic fill/finish manufacturing processes used to manufacture gene therapy products at a site.

About the Role

Responsibilities:

- Supports the collection and interpretation of continued process verification data and collaborate with other departments on manufacturing related issues to drive resolution and process improvements.
- Serve as a scientific and technical representative for process-related issues and investigations at the facility.

- Performs trending and monitoring of critical quality attributes/critical process parameters to maintain product quality and to control process drift.
- Supports tech transfer of new products and processes to ensure smooth transition from process development into GMP manufacturing.
- Looks for opportunities to implement operational excellence and continuous improvement.
- Partners with Quality to ensure a compliant manufacturing environment.
- Assists the technical operations team in resolving issues related to production.
- Partners with manufacturing to meet the production schedule, ensure commercial supply and uphold quality standards.
- Implements potential process improvements in conjunction with operations.
- Participates in start-up efforts of new equipment, software or processes in manufacturing.
- Assists in documenting changes/updates to manufacturing processes and partner with manufacturing, engineering and validation to implement those changes.
- Provides technical/scientific support on project deliverables, i.e. remediation initiatives, plan reports.
- Utilizes small-scale production processes and scaled-down lab processes to enable process troubleshooting.
- Completes requisite training, as well as applicable policies and procedures, related to the job function is an expectation to support ongoing manufacturing support.
- May work on special projects related to development and improvement of business and/or manufacturing processes.

Requirements:

- Bachelor ' s degree in biochemistry, chemical engineering, bioengineering, or related technical field with 4 years of experience in biopharmaceutical based GMP manufacturing operations including direct experience in cell culture, recovery, purification, and/or aseptic fill/finish, or related engineering field.
- Bachelor ' s degree in biochemistry, chemical engineering, bioengineering, or related technical field with 3 years of direct Novartis GTX experience.
- Master of Science degree in biochemistry, chemical engineering, bioengineering, or related technical field with 2 years of experience in support of biopharmaceutical manufacturing, or related engineering field.
- Familiar with global regulations on cGMP manufacturing of drug substance, drug products devices, validation/qualification requirements.
- Strong technical writing ability.
- Proven ability to effectively participate on teams.

#LI-hybrid

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each

other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? <https://www.novartis.com/about/strategy/people-and-culture>

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部门
Operations

Business Unit
Innovative Medicines

地点
USA

站点
Durham

Company / Legal Entity
U473 (FCRS = US473) Novartis Gene Therapies

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work
No

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