

Engineer, Manufacturing Science and Tech

Job ID REQ-10022820 Sep 24, 2024 USA

Summary

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.
- Partners with manufacturing to meet the production schedule, ensure commercial supply and uphold quality standards, and 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.
- Completes requisite training, as well as applicable policies and procedures, related to the job function is an expectation to support ongoing manufacturing support.

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 biopharmageutical 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.

Why Novartis: Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here:

https://www.novartis.com/about/strategy/people-and-culture. The pay range for this position at commencement of employment is expected to be between \$97, 600-146,400 annual; however, base pay offered may vary depending on multiple individualized factors, including market location, job-related knowledge, skills, and experience. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an "at-will position" and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors. You can find everything you need to know about our benefits and rewards in the Novartis Life

Handbook. https://www.novartis.com/careers/benefits-rewards

#LI-hybrid

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Accessibility & Reasonable Accommodations

The Novartis Group of Companies are committed to working with and providing reasonable accommodation to

individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or to perform the essential functions of a position, please send an e-mail to <u>us.reasonableaccommodations@novartis.com</u> or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Division

Operations

Business Unit

Innovative Medicines

Location

USA

Site

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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REQ-10022820

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