

BioProcess Engineer III

Job ID REQ-10038117 Jan 27, 2025 USA

Summary

BioProcess Engineer III

This position will be located at Durham NC site and will not have the ability to be located remotely. If no Relo: "Please note that this role would not provide relocation and only local candidates will be considered."

Summary: The BioProcess Engineer III, is responsible for organizing, running, sustaining, and continuously improving the manufacturing operations process at the plant/site.

Responsibilities:

- Produces clinical and commercial material on an annual basis that meets the site's strategic objectives and is compliant with cGMPs.
- Works on the manufacturing floor to produce product, troubleshoot equipment, and provide ownership for specific pieces of processing equipment.
- Ensures cGMP documentation is being filled out correctly, training is current and all Quality requirements are being followed.
- Participates in tours or information requests for all FDA and internal audits of the manufacturing facilities/processes and respond to any observations received per procedure.
- Maintains quality standards to meet cGMP requirements, CFR's, and internal company policies related to the manufacturing process.
- Supports tech transfer of new products and processes to ensure smooth transition from process development into GMP manufacturing.
- Provides hands on technical leadership to the manufacturing staff members.
- Looks for opportunities to implement operational excellence and continuous improvement.
- Partners with Quality to ensure a quality and compliant manufacturing environment.
- Supports leadership to meet information requirements for quality, compliance, and management reporting.

#LI-Onsite

About the Role

Requirements:

Bachelors of Science Degree in Biology, Chemistry, Biotechnology or applicable field with 2 years' experience in cGMP experience in biologics, pharmaceutical and/or vaccine manufacturing operations, including experience in cell culture, recovery, purification, bulk formulation and/or fill finish environment;

• Five (5) years' experience in cGMP experience in biologics, pharmaceutical and/or vaccine manufacturing operations, including experience in cell culture, recovery, purification, bulk formulation and/or fill finish environment in lieu of degree.

Or

- Bachelors' degree in Biology, Chemistry, Biotechnology or applicable field with 3 year experience in the manufacture of Novartis Gene Therapies product;
- Excellent oral and written communication skills.
- Strong technical writing ability.
- Ability to motivate peers and staff, foster a culture of continuous improvement and operation excellence.
- Experience with 3rd parties (equipment vendors, and contract manufacturing insourcing/outsourcing).
- Project management skill set with experience in strategic/tactical planning, team building, and meeting budgets.
- Ability to routinely lift over 35 lbs.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between: \$66,800 and \$124,000/year; however, while salary ranges are effective from 1/1/25 through 12/31/25, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills, and abilities. 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.

Company will not sponsor visas for this position.

Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers who are focused on building and advancing a culture of inclusion that values and celebrates individual differences, uniqueness, backgrounds and perspectives. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to fostering a diverse and inclusive workplace that reflects the world around us and connects us to the patients, customers and communities we serve.

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

State

North Carolina

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

Apply to Job

Job ID

REQ-10038117

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Apply to Job

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List of links present in page

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