

BioProcess Engineer Downstream/Fill-Finish

Job ID REQ-10042220 May 13, 2025 USA

Summary

This position will be located at Durham, NC and will not have the ability to be located remotely.

The BioProcess Engineer downstream/Fill-Finish is responsible for executing the manufacturing operations at the plant/site. The level of the role will be determined by the years of relevant experience.

#LI-Onsite

Key Responsibilities:

This role is a 2-2-3 day shift position.

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

- Performs commercial and clinical manufacturing operations on the site, including purification (downstream), fill-finish (drug product, visual inspection, packaging), media/buffer preparation, and any additional supporting activities.
- Learns to troubleshoot equipment, participates in interviews on deviations, partners with other business units to assist in manufacturing led deviations, standardizes equipment, and cleans production area.
- Assists in determining root cause, implementing solutions and verifying solutions are effective.
- Assists with the creation and on-going maintenance of all pertinent equipment, policies, and procedures.
- Learn and perform aseptic techniques applicable to cell culture, recovery, purification, aseptic fill/finish (upstream and downstream).
- Supports the product requirements to ensure that all products are produced according to plan. Learn cGMP and cGDP and ensure cGMP documentation is being filled out correctly, training is current, and all quality requirements are being followed.
- Maintains quality standards to meet cGMP requirements, CFR's, and internal company policies directly related to the manufacturing process.
- Partners with the Quality department to ensure a compliant manufacturing environment.

About the Role

Desirable Requirements:

- For BioProcess Engineer I Bachelor of Science Degree in Biology, Chemistry, Biotechnology or applicable field or 2 years equivalent experience;
- For for BioProcess Engineer II Bachelor of Science Degree in Biology, Chemistry, Biotechnology or applicable field and 2 years' experience in cGMP experience in biologics, pharmaceutical and/or vaccine

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manufacturing operations, including experience in cell culture, recovery, purification, bulk formulation and/or fill finish environment; OR four (4) 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;

- For BioProcess Engineer III Bachelor of Science Degree in Biology, Chemistry, Biotechnology or applicable field and 4 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; OR six (6) 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
- Excellent oral and written communication skills
- Entry level into the biopharmaceutical based GMP manufacturing operations, no experience necessary.
- Near vision performance should be the equivalent of 20/20 with no impairment of color vision. The use of corrective lenses to achieve the desired visual acuity is permitted.

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.

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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. 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.

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

Nο

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Job ID

REQ-10042220

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