

Manufacturing BioProcess Engineer I/II/III

Job ID
REQ-10011380
Jul 31, 2024
USA

Summary

The Manufacturing BioProcess Engineer I/II/III downstream/Fill-Finish is responsible for assisting with organizing, running, and sustaining the manufacturing operations process at the plant/site. The level of the role will be determined by the years of relevant experience. Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you. The working hours are 6a-6p on a 2-2-3 rotation.

About the Role

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The Manufacturing BioProcess Engineer downstream/Fill-Finish is responsible for assisting with organizing, running, and sustaining the manufacturing operations process at the plant/site.

Novartis Gene Therapies is dedicated to developing and commercializing gene therapies for patients and families devastated by rare and life-threatening neurological genetic diseases.

- Performs commercial and clinical manufacturing operations on the site, including purification (downstream), fill-finish (drug product), 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.

Role Requirements :

- For BioProcess Engineer I - Bachelor of Science Degree in Biology, Chemistry, Biotechnology or applicable field or 2 years equivalent experience;
- 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 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.
- Ability to routinely lift over 35 lbs.
- Ability to work alternate 12-hour shifts and weekends.
- Approximately 10% travel.

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 \$24.90 and \$37.31 Hourly; 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>

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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 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 us.reasonableaccommodations@novartis.com 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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