U NOVARTIS

Bioprocess Technician/Engineer (Upstream Nights)

Job ID REQ-10030490 Nov 20, 2024 USA

Sommario

The BioProcess Technician/ Engineer I/II/III night shift 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. Working hours 6p-6a 2-2-3 rotation

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

About the Role

Responsibilities:

- Assists in manufacturing led investigations through partnerships with Quality and other business units at the site.
- Produces product, media/buffer preparation, learn to troubleshoot equipment, participate in interviews on deviations, stocking of items in supply/ production / warehouse area, and standardizing equipment and cleaning production area.
- Assists in determine root cause, implement a solution and a verification check to ensure the fix was effective.
- Assists with creation and on-going maintenance of all pertinent equipment, policies, and procedures.
- Produce product, media/buffer preparation, learn to troubleshoot equipment, participate in interviews on deviations, stocking of items in supply/ production / warehouse area, and standardizing equipment and cleaning production area.
- Learn aseptic techniques, cell culture, recovery, purification, aseptic fill/finish (upstream and downstream).
- Assists in producing clinical and commercial material on an annual basis that meets the site's strategic objectives and is compliant with cGMPs.
- Supports the product requirements to ensure that a 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 Quality to ensure a quality and compliant manufacturing environment and assists the technical operations team

Role Requirements :

- For BioProcess Technician High School Diploma or equivalent; Entry level into the biopharmaceutical based GMP manufacturing operations, no experience necessary. Biopharmaceutical training (Bioworks or equivalent) and/or related military training preferred.
- For BioProcess Engineer I Bachelor of Science Degree in Biology, Chemistry, Biotechnology or applicable field or two (2) years' equivalent experience; Entry level into the biopharmaceutical based GMP manufacturing operations, no experience necessary;
- For BioProcess Engineer II Bachelor of Science Degree in Biology, Chemistry, Biotechnology or applicable field and three (3) 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;OR Bachelors' degree in Biology, Chemistry, Biotechnology or applicable field with one (1) year experience in the manufacture of Novartis Gene Therapies product;
- For BioProcess Engineer III Bachelor of Science Degree in Biology, Chemistry, Biotechnology or applicable field and two (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 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;

Other Requirements:

- Excellent oral and written communication skills.
- Direct experience in cell culture, recovery, purification, aseptic fill/finish with working knowledge of FDA regulations and GMP systems preferred.
- Proven ability to effectively lead and participate on teams.
- Ability to routinely lift over 35 lbs.
- Ability to work alternate 12-hour shifts and weekends.
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The pay range for this position at commencement of employment is expected to be between \$24.90 and \$ 37.319 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

#LI-Onsite

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: <u>https://www.novartis.com/careers/benefits-rewards</u>

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.

Divisione Operations Business Unit Innovative Medicines

Posizione USA Stato North Carolina Sito 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

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