NOVARTIS

BioProcess Engineer II/III

Job ID
REQ-10075226
Apr 01, 2026
LOC_US

About the Role

Responsibilities:

- Execute gene therapy upstream/cell expansion manufacturing operations to meet clinical/commercial schedule commitments and cGMP requirements.
- Set up, operate, and monitor single-use upstream equipment and systems (e.g., seed trains/bioreactors, incubators, centrifuges, TFF skids, pumps, tubing/welders/sealers, control systems) in an aseptic/cleanroom environment; perform first-line troubleshooting and escalate issues per procedures.
- Complete real-time cGMP documentation with strong data integrity and traceability (batch records, logbooks, electronic systems as applicable), including material/lot traceability and sample chain-of-custody; ensure training readiness and procedural compliance.
- Support internal and regulatory audits/inspections by compiling requested evidence, providing on-the-floor support, and clearly describing gene therapy manufacturing practices.
- Maintain a safe, clean, and compliant manufacturing environment by following cGMP, EHS, and cleanroom/aseptic behaviors; adhere to contamination control strategy, biosafety practices for viral materials, and proper waste decontamination and disposal.
- Support technology transfer and process start-up/scale-up by executing manufacturing and validation protocols, performing in-process sampling, capturing process parameters, and authoring/updating SOPs, batch records, and training materials in partnership with MSAT/Process Development.
- Drive continuous improvement to enhance safety, quality, and throughput (e.g., 5S, standard work, cycle-time/yield improvements); participate in investigations, root-cause analysis, and CAPA effectiveness to strengthen right-first-time execution.
- Partner with Quality, QC, and cross-functional teams to support deviations, change controls, risk assessments, batch disposition readiness, and environmental monitoring/utilities excursions as applicable, ensuring sustained compliance and product quality.
- Communicate production status and risks through effective shift handovers and escalation; track and report key metrics, ensure timely issue resolution, and maintain material/sample integrity (including temperature-controlled handling when required).

Shift: This role is a 2-2-3 AM shift schedule. 5:45am-5:45pm.

Role Requirements:

*The role level will be determined by years of relevant experience.

Bioprocess Engineer II:

- Bachelor's of Science Degree in Biology, Chemistry, Biotechnology or applicable field with minimum 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

- A minimum 4 years' experience in cGMP 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 1 year experience in the manufacture of Novartis Gene Therapies product;

Bioprocess Engineer III:

- Bachelor's of Science Degree in Biology, Chemistry, Biotechnology or applicable field with minimum 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

- A minimum 6 years' experience in cGMP 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 years' experience in the manufacture of Novartis Gene Therapies product;

Requirements for both levels:

- Excellent oral and written communication skills, including clear shift handover communication and the ability to write compliant, concise documentation (e.g., logbooks, batch record entries, and technical summaries).
- Demonstrated ability to work effectively in a team environment, influence and motivate peers, and foster a culture of safety, quality, continuous improvement, and operational excellence.
- Ability to routinely lift/move materials and equipment up to and including 35 lbs and perform physical tasks associated with manufacturing operations (standing for extended periods, gowning, working with gloved hands, and operating equipment in a cleanroom environment).
- Working knowledge of cGMP principles and data integrity expectations (ALCOA+), with the ability to follow SOPs, execute batch records right-first-time, and escalate issues promptly.
- Experience working in a controlled environment (classified cleanroom) preferred, including aseptic technique, contamination control practices, and operation of single-use assemblies (tubing, filters, sterile connectors, welding/sealing) in accordance with procedures.
- Strong problem-solving skills with the ability to perform first-line troubleshooting, document and communicate issues, and support investigations (deviations) and corrective/preventive actions (CAPA).
- Comfortable using manufacturing business systems and standard software (e.g., electronic documentation systems, equipment interfaces, MS Office); ability to learn new digital tools quickly and use them in a compliant manner.

The salary for this position is expected to range between $32.12 and $59.62 per hour.

The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors.

Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards.

US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

To learn more about the culture, rewards and benefits we offer our people click here

Company will not sponsor visas for this position.

Role Requirements

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

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

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Business Unit
Production / Manufacturing
Location
LOC_US
Site
Durham
Company / Legal Entity
U473 (FCRS = US473) Novartis Gene Therapies
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Full time
Employment Type
Regular
Shift Work
No
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