

Senior/Level III Engineer, Process

Job ID REQ-10049566

4月 29, 2025

USA

摘要

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

The Process Engineer III is responsible for providing engineering, validation and maintenance support to the process manufacturing equipment, facility and utilities at a site.

#LI-Onsite

Key Responsibilities:

- Ensures new equipment is appropriately designed/qualified and existing processes run in a compliant manner through equipment life cycle. Help define and optimize equipment qualification strategy.
- Owns and manages changes to the process equipment to maintain equipment in a validated state.
 Potentially take on a global role in ensuring consistency across manufacturing sites.
- Investigates any equipment or process deviations and developing corrective actions to prevent reoccurrences. Able to provide industry wide expertise for complex equipment and process investigations.
- Participates in all FDA and internal audits of the manufacturing facilities and process equipment as

SME and responds to any observations received.

- Develops and implements equipment reliability and maintenance strategies that are compliant, effective and cost appropriate.
- Applies knowledge of engineering principles and best practices to ensure robust solutions.
- Provides mentorship to other process engineers.
- Leads small internal teams to help optimize engineering systems and processes.
- Independently leads or provide SME support on capital related projects.
- Establishes equipment specifications in standard documentation User Requirements (URS), Functional Specification (FS) and Detail Design Specifications (DDS).

About the Role

Requirements:

The level of the position will be commensurate with education, applicable experience, competency and independence.

Level III

- B.S. degree in Chemical, Electrical or Mechanical Engineering, or related technical field, with 5 years work experience in pharmaceutical or biopharmaceutical based GMP manufacturing operations, or equivalent work experience (9 years) in pharmaceutical or biopharmaceutical based GMP manufacturing operations.
- Excellent oral and written communication skills. Strong technical writing ability required.
- Working in a team environment, with excellent communication and organizational skills.
- Diverse experience in the development, automation, and manufacture of gene therapy products, medical devices, instruments, or biotechnology.

Senior:

- B.S. degree in Chemical, Electrical or Mechanical Engineering, or related technical field, with 8 years work experience in pharmaceutical or biopharmaceutical based GMP manufacturing operations, or equivalent work experience (12 years) in pharmaceutical or biopharmaceutical based GMP manufacturing operations.
- Excellent oral and written communication skills. Strong technical writing ability required.
- Working in a team environment, with excellent communication and organizational skills.
- Diverse experience in the development, automation, and manufacture of gene therapy products, medical devices, instruments, or biotechnology.
- In-depth knowledge of FDA regulations and GMP systems and experience providing

engineering support in a highly regulated or pharmaceutical / biotech facility.

- Strong project management skill set with extensive experience in strategic / tactical planning, demonstrated ability to perform long-term project planning.
- Ability to prepare contingency plans and logically work through complex issues in a pressure filled atmosphere.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between \$89,600 and \$166,400/year for Level III and between \$103,000 and \$192,400/per year for the Senior Levels; 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:

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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.

部门 Operations

Business Unit Innovative Medicines

地点 USA

状态 North Carolina

站点 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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