Process Engineer, III/Senior

Job ID
REQ-10062827

9月 26, 2025

USA

摘要

#LI-Onsite

Location: This role is based in Durham, NC. Novartis is unable to offer relocation support: please only apply if accessible.

Are you ready to shape the future of pharmaceutical manufacturing? As a Process Engineer, Level III/Senior, you ' ll play a pivotal role in ensuring equipment reliability and compliance across its lifecycle. From leading investigations and audits to mentoring engineers and driving global initiatives, your expertise will directly influence operational excellence and innovation. Join us in making a meaningful impact–where your engineering insight fuels better outcomes for patients worldwide.

About the Role

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. Support global initiatives ensuring consistency across manufacturing sites.
- Investigates any equipment or process deviations and developing corrective actions to prevent re-occurrences. 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 lead 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).

Essential Requirements:

The level of the position will be determined based on education, relevant experience, skills, and independence.

Level III Process Engineer

- 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 Process Engineer:

- 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.

AND

- 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.
- Demonstrates skill in developing contingency plans and solving complex problems under pressure.

Novartis Compensation and Benefit Summary:

The salary for this position is expected to range between: ***Level III $89,600 and $166,400; Sr. Level $103,600 and $192,400 per year.*** *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.*

Company will not sponsor visas for this position.

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 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.

部门
Operations

Business Unit
Universal Hierarchy Node

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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