NOVARTIS

Process Engineer III

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REQ-10074861
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США

Сводка

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

The initial responsibilities for this role will be to support the design, build, and qualification of the equipment for a new large molecule drug substance facility. Upon project completion, the role will transition to engineering support and asset lifecycle management of the manufacturing equipment.

About the Role

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 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 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).
- Works closely with operations and manufacturing sciences to evaluate new product introductions and facility fit evaluations.
- Leads small teams to define and advance facility and equipment changes in line with 5- and 10-year strategic plans.
- Leads evaluation of new technologies and equipment platforms for manufacturing.
- Provides engineering, validation and maintenance support to the process manufacturing equipment, facility and utilities at a site; equipment may include major processing equipment such as bioreactors, tangential flow filtration, chromatography, filling equipment, support systems such as incubators, freezers bio-safety cabinets, offline bench-top instruments or facility/utility systems.
- Translates current and future processes into the facility and equipment requirements at a manufacturing site.
- Other related job duties as assigned.

Requirements:

- 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.
- 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.
- Demonstrated ability to lead cross functional teams across manufacturing locations in a fast pace, dynamic team setting.
- Uses professional concepts in accordance with company objectives to solve complex problems in creative and effective ways.
- A seasoned, experienced professional with a full understanding of area of specialization; resolves a wide range of issues in creative ways
- Ability to work on problems of diverse scope where analysis of data requires evaluation of identifiable factors.
- Demonstrates good judgment in selecting methods and techniques for obtaining solutions.
- Networks with senior internal and external personnel in own area of expertise.

Novartis Compensation and Benefit Summary:

The salary for this position is expected to range between $98,700 and $183,300/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.

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)

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.

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