Senior Quality Assurance Engineer

Job ID
REQ-10067141

11月 20, 2025

USA

摘要

The Senior Quality Assurance Engineer is responsible for the design, construction, validation, maintenance and overall compliance of facilities, systems and processes at Novartis Gene Therapies, Durham, N.C.

About the Role

Location:

- This position will be located in Durham, NC and will be able to work on Hybrid schedule

Key Responsibilities:

- Provides QE expertise to support clinical and commercial gene therapy products.

- Full audit support of all internal and external audits in support of product manufacturing.
- Ensures Quality and Compliance aspects of design and work in collaboration with Engineering, technical functions, Manufacturing Operations to ensure that the facility is:
    - Compliant with all appropriate regulations (e.g. FDA, EMEA and other major health authorities) for GMP manufacturing.
    - Capable of manufacturing products that are safe, effective and that meet all applied controls and specifications.
    - Capable to meet intended design goals of output volume, turnaround time and operating and product costs.
- Provides strategic quality input on the translation of commercial product requirements into technical solutions that are capable of meeting defined CQAs (product Critical Quality Attributes) and CPPs (Critical Process Parameters).
- Acts as Quality approver on project deliverables, as defined in the project plan.
- Works with validation colleagues to define the initial asset life-cycle model and qualification and validation strategy, to ensure successful validation of the facility.
- Plays a lead role in the planning, execution and closure of commissioning, qualification and validation activities from a Quality functional perspective.
- Authors and/or approves Standard Operating Procedures in support of project activity and deliverables.
- Provides QA oversight of engineering, validation, and facilities activities related to maintaining a GMP facility in a validated state.
- Acts as the Quality approver of change controls, deviations, and CAPAs required to maintain the manufacturing facility in a GMP state.
- Works with supplier and Vendor Management colleagues to ensure that suppliers of goods and services for the new manufacturing facility are compliant and capable of fulfilling their contracted requirements.

Essential Requirements:

- B.S. degree in preferably engineering, chemistry or biochemistry.
- 7 years of experience in biopharmaceutical based GMP manufacturing operations.
- Experience with viral gene therapies, cell culture technologies and/or orphan disease indications is a plus.
- Strong knowledge and application of the CFR ' s and cGMPs.
- Comprehensive knowledge of FDA and EU regulations and experience in US and international regulatory agency inspections.
- Direct experience with commissioning, qualification and validation to meet FDA and other health authority requirements.
- Experience with deviations, CAPAs, and Change Controls.
- Direct experience reviewing and/or authoring standard operating procedures and partnering with operations on product related investigations and deviations.
- Excellent oral and written communication skills with strong technical writing experience required.
- Ability to synthesize data and summarize outcomes to provide recommendations on compliant path forward

Novartis Compensation and Benefit Summary:

The salary for this position is expected to range between $103,600 and $192,400 annually.

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.

#LI-Hybrid

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: 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 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
Quality

地点
USA

状态
North Carolina

站点
Durham

Company / Legal Entity
U473 (FCRS = US473) Novartis Gene Therapies

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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