NOVARTIS

Head of Quality Control

Job ID
REQ-10039124

2月 06, 2025

USA

摘要

The Head of Quality Control is responsible for designing and implementing innovative and robust processes for testing activities associated with a viral gene therapy manufacturing site which includes bulk product and sterile fill operations.

Location- Durham, NC #LI- onsite

About the Role

Key Responsibilities:

- Develops and executes corporate quality policies, practices, procedures, standards, and systems necessary to ensure adherence to aseptic production and product management in accordance with the cGXP compliance to US and EU regulations.
- Oversees the testing and validation strategy, with a concentrated focus on method verification

and validation.
- Maintains a robust Environmental Monitoring program that meet US/EU and other applicable regulatory requirements.
- Organizes and directs cross functional relationships with Manufacturing, Engineering, MS&T, Quality Assurance, and Regulatory.
- Hires staff and manages contract vendors for programs related to focus area.
- Directs laboratory staff, set goals and expectations, and maintain efficient utilization of resources.
- Authors and approve documents required for regulatory submissions.
- Develops, implements, and ensures laboratory procedures and policies are followed.
- Provides presentations, explain laboratory qualification and operations, and defend testing results during FDA and other inspections.
- Other duties for which QC is responsible, as assigned.

Requirements:

- BS/MS in Microbiology discipline and 12 years of related experience in cGMP laboratory environment, with strong knowledge of regulatory, USP and Eur. Phr guidelines (Ph.D. in life sciences is preferred).
- 8 years of laboratory management experience.
- Experience starting up lab facilities supporting clinical and/or commercial manufacturing.
- Experience with regulatory agency inspections.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $138,600 and $257,400 /year; *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.

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

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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
Innovative Medicines

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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Job ID
REQ-10039124

Head of Quality Control

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