QC Specialist

Job ID
REQ-10054899

6月 27, 2025

USA

摘要

The Specialist, Quality Control, assists and supports the organization with compliance and ongoing preparation, testing and monitoring of conformance to established quality processes and standards for manufacturing and production.

Location: Durham, NC #LI-Onsite
Shift: 2nd

About the Role

Key Responsibilities:

- Executes routine and non-routine analysis for cGMP release and characterization testing using techniques including but not limited to ddPCR, ELISAs, NGS, Western Blot and Bioburden.

- Assists in the evaluation of internal controls, communications, risk assessments and maintenance of documentation as related to compliance with internal and external safety, quality, and regulatory standards.
- Reviews data obtained for compliance to specifications and reports abnormalities. Performs trend analysis of methods /environmental data / assay controls & standards and draws conclusions.
- Capable of delivering to assigned work schedule with attention to detail and accuracy.
- Support department risk assessments and participates in audit walk-throughs.
- Participates in the preparation of investigations, summaries and reports. Reviews data obtained for compliance to specifications and reports Investigates and resolves non-conforming test results by completing thorough Deviation, OOS/OOT/OOE and Investigation.
- Authors new/revise Standard Operating Procedures, Protocols / Summary Reports /Analytical Master Plans for QC.
- Oversees special projects on analytical and instrument problem solving. May develop testing and analysis methods and procedures in accordance with established guidelines.
- Supports training of departmental personnel in appropriate technique and related topics.
- Other related job duties as assigned.

Essential Requirements:

- Bachelor's degree in scientific disciplines such as Biochemistry, Biology, Microbiology or related field with 5 years' experience in GMP environment or 4 years' at GTx
- Excellent interpersonal, verbal and written communication skills with strong technical writing experience required. Previous investigation experience a plus.
- Proven ability to work effectively in a team environment. Collaborates cross functionally with other departments to achieve site goals.
- Works on problems of moderate scope where analysis of situations or data requires a review of a variety of factors.
- Exercises judgment within defined procedures and practices to determine appropriate action including critically thinking, troubleshooting and problem-solving skills.
- Normally receives general instructions on routine work, detailed instructions on new projects or assignments.
- Self-motivated, detail-oriented, and willing to accept temporary responsibilities outside of core duties.

The salary for this position is expected to range between $37.02/hr and $68.75/hr.

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

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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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REQ-10054899

QC Specialist

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