

Specialist, Quality Control - Raw Materials

Job ID
REQ-10073796
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CLIA

Сводка

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

About the Role

Location:

- This position will be located in Durham, NC and will be an On-Site role.
- Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

Key Responsibilities:

- Execute routine and non-routine analysis for cGMP release and characterization testing using techniques including but not limited to chromatography (HPLC, UPLC), AUC, SEC, compendial assays (pH, Conductivity, Osmolality), electrophoresis (CE, Western Blot) and assist with data review.
- Execute method verifications/transfers as required for various projects.
- Assist with enrollment of vendors, ordering reagents and consumables for new assays.
- Initiate all paperwork (LIMS, SOPs, assay forms) for testing and transfers of methods for projects.
- 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 with 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 participate in audit walkthroughs.
- Participates in the preparation of investigations, summaries and reports. Reviews data obtained for compliance with 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.
- Oversee 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 techniques 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 critical 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.

Novartis Compensation and Benefit Summary:

The salary for this position is expected to range between \$41.06 and \$76.25 per hour.

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-Onsite

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.

Дивизион

Operations

Business Unit

Quality

Место

США

Состояние

North Carolina

Сайт

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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