

Quality Control, Specialist

Job ID

REQ-10073806

Mar 18, 2026

LOC_US

About the Role

Key Responsibilities

- Responsible for directing and executing method transfers/verifications and assisting in execution of bioanalytical (BAL) analysis for cGMP release and characterization testing using techniques including but not limited to CE-SDS, SDS-PAGE and CZE methods.
- Supports BAL assay onboarding/execution, including drafts and maintenance of QC SOPs, forms, protocols, reports, Analytical Master Plans and change controls.
- Reviews and approves data for reports and specification compliance; supports and leads resolution of nonconformances (SSFs, deviations, OOS/OOT/OOE investigations)
- Assist with enrollment of vendors, ordering reagents and consumables for new assays.
- 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.
- Performs qualifications, maintenance and trend analysis of bioanalytical methods assays/critical 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.
- 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 or related field required.
- 5 years of experience in GMP environment
- 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.

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.

Role Requirements

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 \(PDF 30 MB\)](#)

Division

DIV_TO

Business Unit

Quality

Location

LOC_US

Site

Durham

Company / Legal Entity

U473 (FCRS = US473) Novartis Gene Therapies

Functional Area

FCT_QA

Job Type

Full time

Employment Type

Regular

Shift Work

No

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