

Sr Analyst, Quality Control Cell-based methods

Job ID
REQ-10040410

2月 19, 2025

USA

摘要

The Senior Analyst, Quality Control, Cell-based methods will support activities within the Quality Control department, with a focus on cell-based methods such as Adventitious Agents, rcAAV, potency, etc. This role will utilize laboratory skills to test and measure product or materials while ensuring that analysis is performed according to established Standard Operating Procedures (SOPs), QC Methods & current Compendia. This role is based 100% on-site.

Location: Durham, NC #LI-Onsite

Shift: 1st. Some night and weekend work may be required

About the Role

Key Responsibilities:

- Executes routine and non-routine analysis for cGMP release and characterization testing

using techniques including but not limited to cell-based methods (potency, AA), PCR (ddPCR, qPCR), Immunoassays (ELISA), chromatography (HPLC-UV, HPLC-ELSD, HPLC-MS), AUC, compendial assays (Bioburden, pH) and electrophoresis (CE, Western Blot).

- Ensures assigned to specific disciplines, but will support all necessary laboratory and assay functions, including housekeeping, safety, logbook/equipment use and maintenance, and updates to existing and authors new operating procedures.
- Capable of delivering to assigned work schedule with attention to detail and accuracy.
- Notifies management, initiates (such as Laboratory Investigations) and authors minor events/discrepancies in the quality systems, with little to no guidance from advisor or management.
- Understands the basic process improvement methodologies, learning and applying concepts of lean lab and six sigma that are applicable to the QC lab environment.
- May facilitate training to other team members in the organization.
- Ensures calibrates and maintains lab and analytical equipment are performed within established period.
- Conducts review of logbooks and may perform reviews as assigned by management
- May assist in drafting technical documents such as Protocols / Report to support method verification/validations.
- Other related job duties as assigned

Essential Requirements:

- Bachelor's degree in scientific disciplines such as Biochemistry, Biology, Microbiology or related field with 2 years ' experience in GMP environment.
- Developing professional expertise, applies company policies and procedures to resolve a variety of issues.
- 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 the critically thinking, troubleshooting and problem-solving skills.
- Normally receives general instructions on routine work, detailed instructions on new projects or assignments.
- Excellent interpersonal, verbal and written communication skills with strong technical writing experience required and ability to work in a team environment.
- Self-motivated, detail-oriented, and willing to accept temporary responsibilities outside of core duties.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between \$32.12/hour and \$59.62/hour; 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.

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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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