

QC Sr. Analyst, Cell-Based Methods

Job ID
REQ-10018707
Sep 03, 2024
USA

Summary

This position 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 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.

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.

The pay range for this position at commencement of employment is expected to be between \$69,300 and \$103,900 per year; however, base pay offered may vary depending on multiple individualized factors, including market location, job-related knowledge, skills, and experience. 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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TEst Hello

Division

Operations

Business Unit

Innovative Medicines

Standort

USA

State

North Carolina

Site

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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