

Senior Manager, QC Cell Based Assays

Job ID

394805BR

Jun 24, 2024

USA

Summary

The Senior Manager, Quality Control is responsible for the day-to-day operations of the internal QC laboratories at the manufacturing or testing site. This position requires direct supervision of staff. Incumbent assures testing is performed in alignment with all relevant quality standards, and ensuring appropriate Quality Control processes, policies, and standard operating procedures to achieve the company's objectives are met.

About the Role

Major accountabilities:

- Develops cooperative and strong working relationships with Manufacturing, Quality Assurance and MS&T to achieve company objectives and direct supervision of staff.
- Ensures that any results generated by internal and external laboratories, are in compliance with GMP.
- Responsible for oversight of routine testing, testing results review and approval and generation of Certificate of Analysis, as required.
- Acts as a subject matter expert for applicable areas.
- Ensures that internal and external laboratories comply with cGMP standards.
- Reviews and approves qualification/validation and routine testing documentation.
- Maximize Quality and process improvements.
- Executed proper investigation into the root cause of product and/or process failures and assists in determining appropriate product disposition and/or process improvements.

Minimum Requirements:

- Bachelor's Degree in Chemistry, Biology or related sciences with 8 years of experience in pharmaceutical industry or equivalent and 2+ years of direct supervisory experience.
- Demonstrated ability to lead in a collaborative environment with a positive leadership style and a hands-on approach that emphasizes teamwork, collaboration, influencing, motivating, and consensus and team building.
- Strong critical thinking, deductive reasoning, and decision-making skills.
- Strong understanding of material sampling, analytical techniques, manufacturing operations, GMPs and the principles behind them.
- Understanding of laboratory equipment such as ddPCR, qPCR, UPLC/HPLC, ICP-MS, UV/Vis Spectrophotometer, Densitometer, Gel Imager, pH, Osmometer, Cell based methods, Microbiology methods, etc.
- Strong ability to work independently and effectively, prioritizing and delivering on tight timelines.
- Approximately 10-15% travel required.

The pay range for this position at commencement of employment is expected to be between \$112,800 and \$169,200 annual; 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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Division

Operations

Business Unit

Innovative Medicines

Location

USA

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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List of links present in page

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