

QC Supervisor, Cell-Based Methods

Job ID
REQ-10018711
Sep 03, 2024
USA

Summary

This position will supervise a team within the Quality Control department, focused on Cell-Based Methods. The supervisor will coordinate sample throughput and compliance activities within the Quality department as well as support development, validation, and external activities as needed.

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:

- Plan/schedule, supervise, and execute/review of in-process, development, validation, and release testing on samples while working with cross-functional stakeholders to meet company quality standards and timelines.
- Support and manage tracking and trending systems, and programs which assist in the testing, evaluation and monitoring of quality, assay performance and efficiency.
- Author, review, and approve Quality documents (i.e., protocols, reports, SOPs, test methods, technical documents, and risk assessments)
- Contribute, support, and lead writing of OOS/OOE/OOT and deviation investigations. Drive CAPA outcomes.
- Support internal and external audits.
- 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.
- Trains and educates employees and promotes adherence to quality control procedures, policies, standards, and best practices to foster a culture of quality awareness and accountability.
- Analyze quality data and metrics to identify trends, patterns, and areas of improvement.
- Promote a culture of continuous improvement, fostering innovation, and implementing Lean techniques to optimize quality control processes and enhance overall operational efficiency.
- Play a key role in the development and growth of direct reports, providing guidance, coaching, and support to enhance their performance and career progression within the organization.

Essential Requirements:

- Bachelor's degree in scientific disciplines such as Biochemistry, Biology or related field with 5 years of experience in pharmaceutical industry or equivalent

- Proven leadership skills with experience in training and mentoring others within a quality laboratory environment.
- Extensive knowledge of GLP and GDocP principles. Understanding of quality management systems (QMS), regulatory requirements (FDA/EMEA), and industry standards.
- Possess a strong understanding of QC testing methods, tools, and techniques.
- Strong analytical and problem-solving skills, with the ability to make data-driven decisions and implement effective solutions.
- Excellent communication and interpersonal skills, with the ability to collaborate with cross-functional teams and effectively communicate quality requirements and findings.
- Detail-oriented and organized, with the ability to manage multiple priorities and meet deadlines.

The pay range for this position at commencement of employment is expected to be between \$92,800 and \$139,200 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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Commitment to Diversity and Inclusion:

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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>

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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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