

Supervisor, Quality Control Microbiology

Job ID
REQ-10061088

9月 16, 2025

USA

摘要

Summary: This position will supervise a team within the Quality Control Microbiology department. 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.

About the Role

Location: Durham, NC

100% on-site, relocation is not being offered at this time.

Key Responsibilities:

- Plan/schedule, supervise, and execute/review of in-process, raw material, development, validation, release, environmental and utility 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. Including the analysis of quality data and metrics to identify trends, patterns, and areas of improvement.
- 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.
- 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.
- Other duties for which QC is responsible, as assigned.

Requirements:

- Bachelor's degree in scientific disciplines such as Biochemistry, Biology or related field with 5 years of experience in pharmaceutical industry or equivalent.
- 1-2 years of prior supervisory experience leading a team is preferred.
- Proven leadership skills with experience in training and mentoring others within a quality laboratory environment.
- Extensive knowledge of GLP/GMP and GDocP principles. Understanding of quality management systems (QMS), regulatory requirements (FDA/EMA), and industry standards.
- Possess a strong understanding of QC testing methods, tools, and techniques (environmental monitoring, sterility, bioburden).
- Experience with room and utility qualifications is a plus.
- 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 \$89,600 and \$166,400/year; 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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Operations

Business Unit
Universal Hierarchy Node

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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