Specialist, Quality Control, Microbiology

Job ID
REQ-10050558

5月 02, 2025

USA

摘要

This position will be located at Durham, NC and will not have the ability to be located remotely.

The Specialist, Quality Control, assists and supports the organization with initial compliance and ongoing preparation, testing and monitoring of conformance to established quality processes and standards for manufacturing and production. The Specialist, Quality Control - Microbiology performs Environmental Monitoring and Microbiological testing in support of manufacturing at the assigned GMP Manufacturing facility, data review and report writing.

#LI-Onsite

Key Responsibilities:
- Executes routine and non-routine analysis, may include, but not limited, to cGMP release and characterization testing using microbial techniques such as environmental and utilities monitoring in clean rooms, bioburden, endotoxin, growth promotion, sterility, and cell culture assays.
- 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.

- Reviews data obtained for compliance to specifications and reports abnormalities. Performs trend analysis of methods / environmental data / assay controls & standards and draws conclusions.
- Capable of delivering to assigned work schedule with attention to detail and accuracy.
- Ensure schedule adherence aligns with department goals and manufacturing support. Escalate as needed.
- Support department risk assessments and participates in audit walk-throughs.
- Compiles data for documentation of test procedures that may include stability program testing and formulation studies.
- Escalate issues with multiple solutions to management when timelines are at risk
- Supports Quality Control department at QMR by preparing slide deck and presenting laboratory metrics.
- Proficient in investigations, summaries and reports. Reviews data obtained for compliance to specifications and reports Investigates and resolves non-conforming test results by completing thorough Deviation, OOS/OOT/OOE and Investigation.
- Authors new/revise Standard Operating Procedures, Protocols / Summary Reports /Trend Reports for QC.
- Oversees special projects on microbial and instrument problem solving. May develop testing and analysis methods and procedures in accordance with established guidelines.

About the Role

Responsibilities

- Bachelor's degree in scientific disciplines such as Biochemistry, Biology, Microbiology or related field with a minimum 5 years ' experience in GMP environment.
- Ability to gown for entry into Aseptic core and supporting areas and lift approximately 25 pounds.
- Raise concerns to management with multiple solutions.
- Acts as SME on cross functional teams and inspection support.
- Full understanding of area of specialization; resolves a wide range of issues in creative ways.
- Works on problems of diverse scope where analysis of data requires evaluation of identifiable factors.
- Demonstrates good judgment in selecting methods and techniques for obtaining solutions.
- Ability to receive little instruction on day-to-day work, general instructions on new assignments.
- Networks with senior internal and external personnel in own area of expertise. **Novartis Compensation and Benefit Summary:** The pay range for this position at commencement of employment is expected to be between $77,000 and $143,000/per year for the Senior Levels; ***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.Company will not sponsor visas for this position.*Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.*

- Bachelor's degree in scientific disciplines such as Biochemistry, Biology, Microbiology or related field with a minimum 5 years' experience in GMP environment.
- Ability to gown for entry into Aseptic core and supporting areas and lift approximately 25 pounds.
- Raise concerns to management with multiple solutions.
- Acts as SME on cross functional teams and inspection support.
- Full understanding of area of specialization; resolves a wide range of issues in creative ways.
- Works on problems of diverse scope where analysis of data requires evaluation of identifiable factors.
- Demonstrates good judgment in selecting methods and techniques for obtaining solutions.
- Ability to receive little instruction on day-to-day work, general instructions on new assignments
- **Novartis Compensation and Benefit Summary:** The pay range for this position at commencement of employment is expected to be between $77,000 and $143,000/per year for the Senior Levels; ***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.
- Company will not sponsor visas for this position.*Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.*Networks with senior internal and external personnel in own area of expertise.

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay

connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we ' ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status.

Accessibility & Reasonable Accommodations

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

Apply to Job

Job ID
REQ-10050558

Specialist, Quality Control, Microbiology

Apply to Job

Source URL:
https://www.novartis.com.cn/careers/career-search/job/details/req-10050558-specialist-quality-control-microbiology

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. mailto:us.reasonableaccommodations@novartis.com
5. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Durham/Specialist--Quality-Control--MicrobiologyREQ-10050558-1
6. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Durham/Specialist--Quality-Control--MicrobiologyREQ-10050558-1