

QC Microbiologist

Job ID
REQ-10019436
Aug 17, 2024
USA

Summary

The QC Microbiologist supports all technical aspects related to quality control testing readiness, including QC reagents and materials management, equipment preparation and daily cleaning and maintenance activities, sample management and QC testing, and documentation completion and review in full compliance with GMP regulation, RLT procedures, and product specifications. Location: Indianapolis, IN #LI-Onsite Multiple positions: Shift: 1st shift Tue- Fri or Thu-Sun

About the Role

Key Responsibilities:

- Finished Product testing, Environmental Monitoring and Sterility QC testing, and reporting of the QC results.
- Escalation in case of non-conformances and deviations and manage these quality incidents as per AAA procedures.
- Support deviation investigations, OOS/OOT/OOE investigations, CAPA follow up and implementation, and Change Control management, including procedure and form revisions.
- Participation in assigned qualification/validation activities, as necessary.
- Responsible for successful on time completion of required training curricula comprising of the necessary Standard Operating Procedures (SOPs) and Aseptic Techniques, Gowning Qualifications, Testing and specifications, and other relevant training including HSE for the specific role.
- Prepares applicable documents, forms, and records such as analytical batch records and follows Good Documentation Practices.
- Support internal and external Audits and Inspections, as required.

Essential Requirements:

- Education: Bachelors' degree required in relevant Scientific discipline (e.g Chemistry, Microbiology).
- Minimum of 3-year experience in cGMP or aseptic environment required.
- Knowledge of cGMP regulations and FDA guidance applicable to Quality Control for product and Environmental Monitoring testing, as well as Aseptic techniques.
- Practical experience with Microbiology method verification and routine testing practices, EM Monitoring and basic knowledge of method/equipment validation principle and methodologies.
- Ability to interpret analytical data and convert into technical documentation.
- Basic knowledge and understanding of aseptic principles and techniques.

The pay range for this position at commencement of employment is expected to be between \$88,000.00 and \$132,000.00 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

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook: <https://www.novartis.com/careers/benefits-rewards>

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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EEO Statement:

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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.

Division

Operations

Business Unit

Innovative Medicines

Location

USA

Site

Indianapolis

Company / Legal Entity

U469 (FCRS = US469) AAA USA Inc.

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

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