

QC Microbiologist

Job ID
REQ-10045451

3月 24, 2025

USA

摘要

About this role:

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, procedures, and product specifications.

Location: Indianapolis, IN #LI-Onsite
Shift: 2nd shift (2PM - Midnight) 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.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between \$81,200-\$150,800/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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部门
Operations

Business Unit
Innovative Medicines

地点
USA

状态

Indiana

站点

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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