

QC Microbiology Manager

Job ID
REQ-10017894
Aug 23, 2024
USA

Summary

Location: Carlsbad, California (on-site) At Advanced Accelerator Applications, a Novartis company, we are committed to leading innovation in nuclear medicine and delivering the next generation of targeted radioligand therapy (RLT) to cancer patients. We are looking for an experienced pharmaceutical industry professional with experience building teams in start-up environments to lead the Microbiology Lab at our new Carlsbad site. As the QC Microbiology Manager, you will be responsible for release testing, reviewing laboratory data, and leading the QC Mirco team.

About the Role

Key Responsibilities:

- Management of Microbiological activities in line with site objectives. Coordination of departmental Operational activities. Track team metrics and ensure KQI /KPI meet requirements.
- Lead OpEx Projects. Support transfer Projects and validation studies.
- New equipment commissioning Support (OQ, PQ). Ensure qualification /calibration status of analytical equipment.
- Investigation of Deviation, OOX, Complaints. Define and implement CAPAs. SOP review and revision.
- Define improvement areas in process and products.
- Perform local training and monitor training status for Microbiological QC. Ensure training according to cGxP requirements.
- Ensure DI and compliance with cGxP and all regulatory requirements. Collaboration in GxP internal audits and ensure fulfillment of internal/external audit and inspection plans.
- Management of documentation and Methods according to cGxP.
- Ensure compliance of products and other materials with specifications and with corporate, health authorities, and E5 requirements
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt.

Essential Requirements:

- BS in Microbiology or relevant scientific field
- 5 years of experience in a GMP quality control microbiology environment involved with environmental monitoring of clean rooms, isolator sterility testing, gram staining, bioburden, endotoxins, etc.
- 2 years of experience in a people management role.

Desirable Requirements:

- Advanced degree

The pay range for this position at commencement of employment is expected to be between \$118,400 and \$177,600 per year; however, while salary ranges are effective from 1/1/24 through 12/31/24 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.

Benefits and rewards: Read our handbook to learn about all the ways we’ll help you thrive personally and professionally: [Thrive Together \(novartis.com\)](https://www.novartis.com).

Commitment to Diversity and Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

#LI-Onsite

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 who are focused on building and advancing a culture of inclusion that values and celebrates individual differences, uniqueness, backgrounds and perspectives. 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. We are committed to fostering a diverse and inclusive workplace that reflects the world around us and connects us to the patients, customers and communities we serve.

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

Carlsbad (California)

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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