

QC Microbiology Manager

Job ID
REQ-10017894
Aug 02, 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 \(novartis.com\)](#)**.

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>

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Division

Operations

Business Unit

Innovative Medicines

Location

USA

Site

Remote Position (USA)

Company / Legal Entity

U469 (FCRS = US469) AAA USA Inc.

Alternative Location 1

Carlsbad, USA

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

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EEO Statement :

Learn about our business, strategy and performance in 2023, and how we create sustainable value for stakeholders and society.Learn about our business, strategy and performance in 2023, and how we create sustainable value for stakeholders and society.Learn about our business, strategy and performance in 2023, and how we create sustainable value for stakeholders and society.Learn about our business, strategy and performance in 2023, and how we create sustainable value for stakeholders and society.

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Major Accountabilities ~ Steigern Sie Ihr wettbewerbsfähiges Umsatzwachstum ~ Identifizierung und Priorisierung von Kunden mit hohem Potenzial durch Datenanalyse (HCPs und Stakeholder), die Verschreibungsentscheidungen beeinflussen ~ Steigern Sie die Vertriebsleistung durch die geschickte Orchestrierung positiver Kundenerlebnisse ~ Engagieren und Beziehungen aufbauen ~ Führen Sie wertorientierte Gespräche (persönlich und virtuell), um kritische Kundenherausforderungen, Entscheidungstreiber, Schwachstellen und Chancen zu verstehen ~ Personalisieren und orchestrieren Sie Customer Engagement Journeys für HCPs,

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