

QA Operations Manager

Job ID
REQ-10001445
Apr 11, 2024
USA

Summary

The QA Operations Manager is responsible for quality assurance oversight of manufacturing, testing and supply chain operations with current GMP regulations, procedures and quality systems. Provide Leadership and manage Quality Assurance Managers in all quality related matters and to ensure that all aspects of the operational business comply with cGMP (Current Good manufacturing Practices) legal and regulatory requirements and the Novartis Quality Manual and Policies. Ensure that all products manufactured by site/External Supplier in addition to the imported products for local site are released to the market according to Novartis Quality Standards.

About the Role

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- Provide shop floor oversight of all production, quality control and supply chain departments to ensure their practice fully adheres to cGMP, including data integrity. Ensure timely escalation to management of all applicable incidents.
- Ensure the Quality Operations team is fully staffed to support operations within supply chain, technical operations and the laboratories across all scheduled shifts. Hire and supervise internal and external staff.
- Provide daily leadership and management for the QA Operations Team.
- Perform live review of manufacturing batch records in preparation for batch release and escalate any discrepancies immediately.
- Assist functional areas with achieving timely and compliant final product disposition of the product.
- Support FDA/Regulatory interactions for the Indianapolis site activities and products to ensure successful regulatory submissions and inspections.
- Review, approve and support procedures investigations, corrective and preventive actions, change controls, complaints, training and production/testing records as required.
- Support QA Operations as a valued business partner, with a culture of safety, quality, delivery to patients, cost, compliance and data integrity.
- Establish site Sterility Assurance program, implement governance to ensure compliance of site personnel and application of aseptic techniques, Site Microbiological control strategy and trending (EM and Product) and full compliance to sterile manufacturing regulations.

- Other related duties as assigned.

Minimum requirements:

- Bachelor's Degree, preferably in Life Sciences, Chemistry or related relevant degree.
- 5+ years of experience in a GxP manufacturing operations environment.
- 2+ years of experience in aseptic GMP manufacturing is preferred.
- 2+ years of experience in a quality assurance role is required.
- Excellent communication skills
- Previous leadership experience is preferred.

The base pay amount for this position at commencement of employment is expected to be between 112,800-169,000 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.

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Division

Operations

Business Unit

Innovative Medicines

Standort

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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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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