Quality Assurance Operations Specialist

Job ID
REQ-10042247
Mar 05, 2025
USA

Summary

Our QA Operations Specialist manages Quality aspects and projects within area of responsibility as well as ensuring and supporting overall GxP conformity and Compliance with the Novartis Quality Management Systems for the Millburn manufacturing site.

Location: Millburn #LI-Onsite

Shift: Week 1: Sun-Wed AM (6:00am-5:30pm)
Week 2: Sun-Tue AM (6:00am-6:30pm)

About the Role

Key Responsibilities:

o Provide shopfloor quality 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.

o Perform live review of manufacturing/packaging batch records in preparation for batch release and escalate any discrepancies immediately.

o Assist functional areas with achieving timely and compliant final product disposition of the product and ensure compliance of site personnel according to current procedures and GMP requirements

o Review, approve and support Deviations, change controls, CAPAs, procedures, production/testing MBRs as required.

o Support FDA/Regulatory interactions for the Indianapolis Isotopes site activities and Isotopes products to ensure successful regulatory submissions and inspections.

o Support QA Operations as a valued business partner, with a culture of safety, quality, delivery to patients, cost, compliance and data integrity.

o Support continuous quality improvement program for manufacturing operations and partner with the production, engineering, and supply chain teams to implement/optimizes to improve efficiency (right the first time) and monitor/escalate as needed.

o Supports QA Operations programs especially related to batch release activities and shop floor programs which includes Visual Monitoring on Surprise (ViMOS), GEMBA walkthrough program, equipment/area/utility

out of service program, QA area release of classified and unclassified areas, QA media fill oversight programs, event triage and support of routine operations.

Essential Requirements

Education: Bachelors' Degree, preferably in Life Sciences, Chemistry or related relevant degree. Experience:

· 2+ years of experience in a GxP (Bio)pharmaceutical or API manufacturing operations

· 1+ years of experience in a quality assurance role

· Collaborating across boundaries

· Functional Breadth

· QA and/or QC experience in pharmaceutical industry with environmental monitoring & cleanliness zones

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $81,200 and $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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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.

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Quality Assurance Operations Specialist

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