QA Operations Specialist

Job ID
REQ-10049926

May 15, 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: Wednesday- Saturday PM
Week 2- Thursday-Saturday PM

About the Role

Key Responsibilities:

- Batch Record Review and Release:
    - Review/approve investigations of excursions in production, engineering, and supply chain operations.
    - Support resolution of major and critical quality events, monitor that recurrent events are properly escalated and resolved.
    - Ensure root cause is determined, evaluate impact on product quality, disposition, and corrective actions.
    - Perform final review of production data test data/reports to ensure conformance to the established specifications and standard operating procedures.
    - Act as Responsible Person for the final disposition of products.
    - Follow the scheduling of tasks set forth by the QA operations Lead or Head for batch record issuance and record review and release activities.
- Provide QA support of production, engineering, and supply chain operations through review/approval of test records for batch release, SOPs, CAPAs, Deviations, change controls, and shop floor oversight.
- Provides the production, engineering, and supply chain teams with QA/Compliance guidance and decisions.
- Review and approve Standard Operating Procedures, Quality Risk Assessments, Quality Plans related to manufacturing operations, as needed.
- Contribute to generation of Annual Product Reviews for production, engineering and supply chain.
- Support continuous quality improvement program for manufacturing operations and partner with the production, engineering, and supply chain teams to implement/optimizes to improve efficiency and monitor/escalate as needed.
- Supports all regulatory inspections related to preparedness initiatives and executions of the inspections.
- Provide cGMP and associated OJT training to any other quality members and other operational areas as needed.
- Perform or support any other tasks necessary to maintain the product quality and site cGMP compliance, as needed.

Essential Requirements

- Education: Bachelors' Degree, preferably in Life Sciences, Chemistry or related relevant degree
- 3+ years of experience in a GxP (Bio)pharmaceutical or API manufacturing operations
- 2+ 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.

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. 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.

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.

部門
Operations

部門
Innovative Medicines

国
USA

State
New Jersey

勤務地
Millburn

Company / Legal Entity
U469 (FCRS = US469) AAA USA Inc.

Functional Area
Quality

職種
Full time

雇用形態
Regular

Shift Work
No

Apply to Job.

Job ID
REQ-10049926

QA Operations Specialist

Apply to Job.

Source URL:
https://prod1.novartis.com/jp-ja/careers/career-search/job/details/req-10049926-qa-operations-specialist

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. mailto:us.reasonableaccommodations@novartis.com
5. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Millburn/QA-Operations-SpecialistREQ-10049926-1
6. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Millburn/QA-Operations-SpecialistREQ-10049926-1