NOVARTIS

QA Operations Specialist

Job ID
REQ-10031557
Dec 03, 2024
USA

Summary

This is an exciting opportunity to join our Quality Assurance Team as a QA Operations Specialist. You will be responsible for quality assurance oversight of manufacturing, testing and supply chain operations with current GMP regulations, procedures and quality systems.

Location: Indianapolis, NJ #LI-Onsite
Shift: 6pm-6am Monday-Thursday

About the Role

Key Responsibilities:

• Provide shop floor 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.
• 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.
• Review, approve and support procedures and production/testing records as required and assist in the training of site associates.
• Ensure compliance of site personnel and application of aseptic techniques and full compliance to sterile manufacturing regulations.
• Support FDA/Regulatory interactions for the site activities and products to ensure successful regulatory submissions and inspections.
• Support QA Operations as a valued business partner, with a culture of safety, quality, delivery to patients, cost, compliance and data integrity.

Essential Requirements

Bachelors' Degree, preferably in Life Sciences, chemistry or related relevant degree preferred. In lieu of degree, three years of experience in GxP Quality may be considered.
Experience:
2+ years of experience in a GxP Biopharmaceutical manufacturing operations
1+ years of experience in a quality assurance role preferred
Experience working in a matrixed organization

QA and QC experience in biotech pharmaceutical industry with environmental monitoring & cleanliness zones

The pay range for this position at commencement of employment is expected to be between $88,000.00 and $132,000.00 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

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

State
Indiana
Site
Indianapolis
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Job Type
Full time
Employment Type
Regular
Shift Work
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Job ID
REQ-10031557

QA Operations Specialist

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