NOVARTIS

QA Manager Operations

Job ID
REQ-10019521
Ago 22, 2024
Estados Unidos

Resumen

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. The QA Operations Manager 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. Location: Indianapolis, IN #LI-Onsite Shift: Wed-Sun, 1st

About the Role

Key Responsibilities:

- 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.

Essential 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 - $169,200 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.

You’ll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook: https://www.novartis.com/careers/benefits-rewards

Commitment to Diversity and Inclusion:

The Novartis Group of Companies are Equal Opportunity Employers and take pride in maintaining a diverse environment. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, gender, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people.

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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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.

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