QA Operations Specialist

Job ID
REQ-10059374

8月 04, 2025

USA

摘要

About this role:

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 Indianapolis manufacturing site.

Location: Indianapolis #LI-Onsite

Must be flexible with schedule
- Shift Hours: Weekday Night shift from 2PM to 2 AM.
- Work Schedule: Rotating workweek with a mix of 4-day and 3-day work periods.

Schedule Breakdown:
- Week 1: Work Monday to Thursday (4 days), then have 3 days off (Friday to Sunday).
- Week 2: Work Monday to Wednesday (3 days), then have 4 days off (Thursday to Sunday).

About the Role

Key Responsibilities:

- 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.
- 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 Indianapolis 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.
- Other related duties as assigned.

Essential Requirements

- Bachelors' Degree, preferably in Life Sciences, chemistry, or related relevant degree. In lieu of degree, 3-5 years in a role within pharma industry that includes quality assurance experience will be considered
- 2+ years of experience in a GxP Biopharmaceutical manufacturing operations
- 1+ years of experience in a quality assurance role
- Cross functional collaboration
- QA and QC experience in biotech pharmaceutical biotechnology industry with environmental monitoring & cleanliness zones is desired
- Proven track record and practical experience with cGMP requirements
- Knowledge of FDA and EU regulations and experience in US and international regulatory agency inspections.

The salary for this position is expected to range between $81,200 and $150,800/year. The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors. Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards.

US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

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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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.

部门
Operations

Business Unit
Innovative Medicines

地点
USA

状态
Indiana

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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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