NOVARTIS

QA Operations Specialist

Job ID
REQ-10037867
Jan 24, 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 Indianapolis Isotopes manufacturing site.

Location: Indianapolis #LI-Onsite
Shift: This position involves shift work which will be defined through site start up and commercialization readiness. This position involves on-call shifts, if required, when scheduled

About the Role

Key Responsibilities:

- Supports the qualification, validation and operational readiness of the ongoing expansion in Indianapolis Isotopes manufacturing site.
- As the project progresses, this role will transition to provide shopfloor QA support and oversight of GMP operations during qualification and validation runs, and other related job duties as assigned.
- Once the site is operational the role accountabilities will transition to:
  - 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 and ensure compliance of site personnel according to current procedures and GMP requirements
  - Review, approve and support procedures and production/testing records as required and assist in the training of site associates.
  - Support FDA/Regulatory interactions for the Indianapolis Isotopes site activities and Isotopes 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.
  - During the initial project expansion project phase, the role will be in daytime. The role will move to shift work once qualification and validation activities start and during the operational manufacturing once the site is approved

Essential Requirements

- Bachelors' Degree, preferably in Life Sciences, Chemistry or related relevant degree.

- 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.

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.

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QA Operations Specialist

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