Lead, QA Operations

Job ID
REQ-10037865
Ene 24, 2025
Estados Unidos

Resumen

The role is responsible for the quality oversight of Production and Quality Control testing at Indianapolis Isotopes, including final disposition of product. This role ensures that the quality strategy is implemented and that there is a continuous drive to improve product and process quality within the Production Unit. The role is responsible of supporting the site construction, qualification, validation and operational readiness from an operational quality perspective.

Location: Indianapolis #LI- Onsite
Position will initially be an AM shift, however, the work schedule will be defined through site start up and commercialization readiness.

About the Role

Key Responsibilities:

- QA oversight of technical activities related to commissioning, qualification, and process validation (Current ongoing expansion) As the project progresses, this role will transition to providing leadership, daily support, and oversight of GMP operations.
- Support the development of the overall site operational readiness plan including implementation of Quality Systems and Processes to ensure product quality, adherence to GMP and compliance with Novartis standards.
- Support initial recruiting, and build capability, for a quality assurance staff to support qualification, validation, and routine production.
- Responsible for quality oversight on overall laboratory readiness activities including equipment qualification, test method validation/co-validation/transfer, test method qualification/verification.
- Lead cross functional groups and build collaborative interfaces with stakeholders to ensure quality systems such as deviation management, investigations, corrective and preventive actions, change control and complaint management are in place and followed.
- Support Isotopes/API FDA/Regulatory interactions for the Indianapolis site activities and products to ensure successful regulatory submissions and any commercial field actions.
- Ensure preparation and delivery of relevant Validation Plans.
- Act as Responsible Person for the final disposition and release of products. Ensure timely and compliant final product disposition of the Product.
- Ensures that deviations, OOx, CAPA’s or any other record is reviewed and approved in a timely manner
- Ensure the coaching and training of the quality team and other site function’s associates.
- Actively support audits/inspection management as well as the setup/maintenance of inspection readiness program.

- QA and/or QC experience in pharmaceutical industry with environmental monitoring & cleanliness zones

Essential Requirements

- Minimum of a bachelor's degree or higher in Pharmacy, Biochemistry, Chemistry, Biology, Engineering or other related life science degree.
- 7 years' experience in the pharmaceutical industry with direct experience with Compliance, Quality Systems and sterile manufacturing.
- Previous Managerial experience in Quality Assurance
- Experience in Starting materials and API clinical, manufacturing, outsourcing and/or other relevant operational areas which must include Quality Assurance
- Thorough knowledge of GMP requirements
- Strong understanding of regulatory Quality Systems requirements
- Proven track record with FDA, EMEA and other Health Authorities
- Strong understanding of risk assessment and risk management fundamentals/tools
- Team building and process harmonization skills.
- Proven leadership skills to drive quality improvement and guide changes.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $93,800 and $174,200/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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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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