QA Batch Release Technician

Job ID REQ-10064500

10月 21, 2025

USA

摘要

About this role:

The QA Batch Release Technician is responsible for the quality assurance release of radioligand therapy drugs manufactured, packaged and tested in compliance to current GMP regulations, procedures and quality systems.

Location: Indianapolis, IN #LI-Onsite Shift: Monday-Friday 9 AM - 5 PM

Novartis is unable to offer relocation support for this role. Please only apply if the location is accessible for you.

About the Role

Key Responsibilities:

- Perform release of all manufactured, packaged and tested materials including but not limited to raw materials, intermediates and drug products. Confirm all documentation supporting these releases fully adhere to cGMP, including data integrity. Ensure timely escalation to management of all applicable incidents.
- Controlled issuance of batch records in preparation for manufacturing.
- Perform 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.
- Ensure Specifications in place and are within GMP compliance.
- Support QA Batch Release as a valued business partner, with a culture of safety, quality, delivery to patients, cost, compliance, and data integrity.
- Organize and file all executed and associated GMP documentation (e.g. batch records).
- Maintain batch documentation library (record check-in, check-out, follow-up, and distribution).
- Other related duties as assigned.

Essential Requirements:

- Bachelors' Degree, preferably in Life Sciences, chemistry, or related relevant degree preferred.
- 1+ years of experience in a GxP Biopharmaceutical manufacturing operations preferred with Bachelor's degree
- 1+ years of experience in a quality assurance role preferred with Bachelor's degree
- In lieu of Bachelor's Degree, at least 5 years of relevant QA experience within pharmaceutical GMP QA considered.
- · Cross functional collaboration
- Functional Breadth
- 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.

Novartis Compensation and Benefit Summary: The salary for this position is expected to range between \$30.58/hr and \$56.83/hr. 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

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:

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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.

部门 Operations

Business Unit Innovative Medicines

地点

状态 Indiana

站点 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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