QA Batch Release Specialist

Job ID
REQ-10054570

6月 10, 2025

USA

摘要

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

Location: Indianapolis, IN 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.

2 positions available

About the Role

Key Responsibilities:

- During project startup, 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 perform release of all manufactured, packaged and tested materials including but not limited to raw materials, intermediates and finished API starting materials. 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 metric tracking of documentation and release data to ensure continuous improvement.
- Support QA Batch Release as a valued business partner, with a culture of safety, quality, delivery to patients, cost, compliance, and data integrity.
- CAPA management as well as improving processes within QA Batch release
- 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)
- Support QA Operations by providing shopfloor quality oversight of production, quality control and supply chain departments to ensure adherence to cGMPs, including 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. In lieu of degree, 3-5 years in a role within pharma industry that includes quality assurance and batch release 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 $158,00 per 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

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:

The Novartis Group of Companies are Equal Opportunity Employers. 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.

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
USA

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

Apply to Job

Job ID
REQ-10054570

QA Batch Release Specialist

Apply to Job

Source URL:
https://prod1.novartis.com.cn/careers/career-search/job/details/req-10054570-qa-batch-release-specialist

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. mailto:us.reasonableaccommodations@novartis.com
5. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Indianapolis/QA-Batch-Release-SpecialistREQ-10054570-1
6. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Indianapolis/QA-Batch-Release-SpecialistREQ-10054570-1