

QA Batch Release Specialist

Job ID
REQ-10042686
Mar 03, 2025
USA

Summary

The QA Batch Release Specialist 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: 2nd shift- Wednesday- Sunday 2:30pm-11:00pm

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 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)

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.

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>

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.

Division
Operations
Business Unit
Innovative Medicines
Location

USA
State
Indiana
Site
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-10042686

QA Batch Release Specialist

[Apply to Job](#)

Source URL: <https://uat2.novartis.de/de-de/careers/career-search/job/details/req-10042686-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/Novartis_Careers/job/Indianapolis/QA-Batch-Release-Specialist_REQ-10042686-1
6. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Indianapolis/QA-Batch-Release-Specialist_REQ-10042686-1