

QA Batch Release Specialist

Job ID
REQ-10054570
Jun 10, 2025
USA

Summary

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.

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<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.

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

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