

QA Batch Release Specialist

Job ID
REQ-10035672
Jan 09, 2025
USA

Summary

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

Location: Indianapolis, IN #LI-Onsite
Shift: 2nd shift; days will vary

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)
- Other related duties as assigned.

Essential Requirements:

- Bachelors' Degree, preferably in Life Sciences, chemistry, or related relevant degree. In lieu of degree, 5 years in a role within pharma industry that includes quality assurance will be considered.
- 2+ years of experience in a GxP Biopharmaceutical manufacturing operations
- 1+ years of experience in a quality assurance role
- Experience with Raw Material release preferred.
- 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

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