NOVARTIS

QA Batch Release Technican

Job ID
REQ-10017755
Aug. 01, 2024
USA

Zusammenfassung

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: 2nd, Friday-Tuesday

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).

Essential Requirements:

- Bachelors' Degree, preferably in Life Sciences, chemistry, or related relevant degree preferred. In lieu of degree, at least 5 years of relevant QA experience within pharmaceutical GMP QA considered.
- 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.

- 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.

The pay range for this position at commencement of employment is expected to be between $59,900 and $89,900 per year; however, base pay offered may vary depending on multiple individualized factors, including market location, job-related knowledge, skills, and experience. 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.

You’ll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook: https://www.novartis.com/careers/benefits-rewards

Commitment to Diversity and Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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

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

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EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers who are focused on building and advancing a culture of inclusion that values and celebrates individual differences, uniqueness, backgrounds

and perspectives. 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. We are committed to fostering a diverse and inclusive workplace that reflects the world around us and connects us to the patients, customers and communities we serve.

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.

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Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job
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