QA Batch Release Specialist

Job ID
REQ-10015046
Juli 12, 2024
USA

Zusammenfassung

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

About the Role

Location: Indianapolis #LI-Onsite

Shift: 3rd, Friday-Tuesday

About this role:

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.

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 preferred. In lieu of degree, prior Novartis experience and 7 years in a similar role within pharma quality assurance 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 pay range for this position at commencement of employment is expected to be between $97,600 and $146,400 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.

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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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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