Quality Control Specialist - Raw Materials

Job ID
REQ-10048861

4月 15, 2025

USA

摘要

We are seeking a detail-oriented and proactive Quality Control (QC) Specialist to support raw material testing within both Microbiology and Chemistry disciplines at our Indianapolis facility. This site plays a critical role in the production of Lutetium Chloride; a key component used in radiopharmaceutical therapies. The QC Analyst will be responsible for sampling, testing, and releasing raw materials to ensure compliance with applicable regulatory standards and internal specifications. This is a hands-on role that requires strong analytical and microbiological skills, GMP knowledge, and a collaborative mindset to help support the site's quality and production goals.

About the Role

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Location: Indianapolis, IN #LI-Onsite

Shift: This position involves shift work which will be defined through site start up and commercialization readiness.

Key Responsibilities:

Demonstrates technical experience in aspects related to quality control testing as well as material transfers to and from third party laboratories or other Novartis sites. Cross collaboration, support and technical insight for material requirements are fundamental for this role. Ensuring documentation completion remains in full compliance with GMP regulations, Novartis procedures, and product specifications.

- Coordinate with third-party laboratories for raw material testing that cannot be performed in-house (e.g., advanced ID tests).
- Prepare and manage sample shipments, ensure proper documentation, and track turnaround times to meet deadlines.
- Review and assess external lab results for accuracy and compliance with specifications.
- Executes analytical testing for radioisotopes and incoming materials.
- Ensure all testing is performed within required timelines to support material release and production schedules.
- Work closely with Quality Assurance, Supply Chain, Production, and Warehouse teams to ensure the efficient flow and release of raw materials.
- Provide technical support and expertise in resolving raw material-related issues that impact production or quality timelines.
- Supports deviation investigations and OOS/OOT/OOE investigations with testing, if needed.
- Supports internal and external Audits and Inspections, if needed.

Essential Requirements:

- Education: Bachelor's degree in chemistry microbiology or a related field.
- A minimum of 2 years of experience in a cGMP environment with prior Quality Control and analytical chemistry experience.
- Adaptability to cross training in microbiology techniques to support activities related to raw materials like growth promotion.
- Experience working with external testing laboratories is highly desirable.
- Solid understanding of USP/EP testing methods, raw material release requirements, and quality control principles.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $89,600/year and $166,400/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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U469 (FCRS = US469) AAA USA Inc.

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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