

# Production Lead

Job ID  
REQ-10030824  
Nov 25, 2024  
USA

## About the Role

### Key responsibilities:

- Execute all activities related to the manufacturing of RLT isotope products, including operating and maintaining grade C isolators, focusing on KPI goals and ensuring adherence to all state, federal and Novartis radiation safety guidelines.
- Completion of required training curriculum comprising necessary Standard Operating Procedures (SOPs) and Techniques, Gowning Qualifications and other relevant training including role-specific Health, Safety & Environment training. Ensure Production Technicians complete all required training in accordance with published curriculum.
- Support all technical aspects related to production readiness including cleaning the cell and sterilizing the isolators.
- Conduct routine and dynamic environmental monitoring as required.
- Prepare all materials while maintaining material identity in accordance with the batch monitoring system as defined by procedure.
- Participate in assigned qualification/validation activities.
- Facilitate a “speak up” culture. Ensure all cGMP compliance activities are followed.
- Prepare applicable documents and records such as batch records, shipping documents, and training materials.
- Participate in periodic mandatory overtime to ensure process continuity and completion.
- Partner with leadership in professional development counselling to foster a growth culture.

### Essential Requirements:

- Bachelor of Science degree is strongly preferred. In lieu of degree, a minimum of 2 years of experience in a cGMP or aseptic environment can be substituted.
- 4+ years of experience in pharmaceutical manufacturing, with low bioburden manufacturing preferred.
- Good understanding of manufacturing and validation requirements and activities
- Ability to utilize new technology and techniques to eliminate non-value adding activities and improve productivity / performance through new processes.
- Proficient in MS Office applications.

### Desirable Requirements:

- Training in radiochemistry or radio pharmacy is preferred.
- Knowledge of cGMP regulations and FDA guidance applicable to radioligand therapy or isotope

manufacturing.

#LI-Onsite

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**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.

The pay range for this position at commencement of employment is expected to be between \$40.38 and \$60.57 per hour; however, while salary ranges are effective from 1/1/24 through 12/31/24 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.

## Role Requirements

**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.

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Division

Operations

Business Unit

Innovative Medicines

Location

USA

Site

Indianapolis

Company / Legal Entity

U469 (FCRS = US469) AAA USA Inc.

Functional Area

Technical Operations

Job Type

Full time

Employment Type

Regular

Shift Work

No

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