

Production Lead (Nights)

Job ID
REQ-10050887
May 05, 2025
USA

Summary

Production Leads play an active role in daily production of isotope manufacturing as well as setup and preparation of instruments and equipment. The Production Lead adheres to regulatory requirements while performing job functions, executing production as per batch records and SOPs. Responsibilities are performed within a team and according to an assigned production shift schedule. The Production Lead works closely with the Production Manager and Shift Supervisor to ensure production is executed in a safe and timely manner. This role will transition to night shifts in the future.

About the Role

Major accountabilities:

- Executes all activities related to the manufacturing of RLT isotope products. Responsibilities include operating and maintaining grade C isolators, focusing on KPI goals as well as ensuring all state, federal and Novartis radiation safety guidelines are adhered to.
- Responsible for successful on time completion of required training curriculum comprising of the necessary Standard Operating Procedures (SOPs) and Techniques, Gowning Qualifications and other relevant training including HSE for the specific role.
- Supports all technical aspects related to production readiness including manually cleaning the cell and performing sterilization of the isolators.
- Conducts routine and dynamic environmental monitoring as required.
- Prepares all materials while maintaining material identity in accordance with the batch monitoring system as defined by procedure.
- Participation in assigned qualification/validation activities, as necessary.
- Facilitates a culture of “speaking up” and ensuring all cGMP compliance activities are followed.
- Prepares applicable documents and records such as batch records, shipping documents, and training materials.
- Participates in periodic mandatory overtime to ensure process continuity and completion.
- Ensures technicians complete all required training in accordance with published curriculum.
- Participate in technician professional development counselling to foster a growth culture.
- Other duties may be assigned, as necessary.

Essential Requirements:

- Training in radiochemistry or radio pharmacy is preferred.
- 4+ years of experience in pharmaceutical manufacturing, with low bioburden manufacturing preferred.
- Good understanding of manufacturing and validation requirements and activities.
- Exploitation of new technology and techniques to eliminate non-value adding activities and improve

productivity / performance through new processes.

- Knowledge of cGMP regulations and FDA guidance applicable to isotope manufacturing.
- Proficient in MS Office applications.
- Flexibility to don clean room garments and personal protective equipment (PPE).
- Near vision performance should be the equivalent of 20/20 with no impairment of color vision. The use of corrective lenses to achieve the desired visual acuity is permitted.
- Makeup, jewelry, nail polish, perfume/cologne and other potential microbial sources are prohibited in restricted areas.
- Ability to lift or carry up to 35 pounds.
- Bachelor of Science strongly preferred. If the applicant does not have a degree, a minimum of 2 years of experience in a cGMP or aseptic environment can be substituted

#LI-Onsite

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The pay range for this position at commencement of employment is expected to be between \$77,000 and \$143,000 per 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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Division

Operations

Business Unit

Innovative Medicines

Location

USA

State

Indiana

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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