NOVARTIS

Production Lead, Weekend Days

Job ID
REQ-10068829
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США

Сводка

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 to ensure production is executed in a safe and timely manner.

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.

Minimum Requirements:

- 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.
- 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.
- 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.

Shift: Weekend days, 12 hours

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

Benefits and Rewards: Learn about all the ways we’ll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

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Production / Manufacturing

Место
США
Состояние
Indiana
Сайт
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Company / Legal Entity
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Functional Area
Technical Operations
Job Type
Full time
Employment Type
Regular
Shift Work
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