Production Lead

Job ID
REQ-10068192

12月 04, 2025

USA

摘要

The Production Lead is responsible for the daily operations, specifically to direct, manage operations related to the Production Unit to produce and deliver product with high quality, in a compliant, efficient, and cost-effective manner while safety is maintained.

About the Role

Key Responsibilities:

- Ensure batches are executed and records all applicable data in compliance with cGMP expectations.
- Author and review Standard Operating Procedures that pertain to Production-related activities.
- Engage with Production Management and Process Experts to identify and implement process improvements within areas of expertise.

- Maintain an "audit ready" module. Assist with internal pre-audits walkthroughs, cGMP housekeeping and general organization and upkeep of manufacturing spaces.
- Assist Production Manager with communication of job-related information during daily meetings and organize the team for daily activities.
- Supervise training to ensure new hires have necessary technical skills and knowledge.
- Adhere to all SOPs, cGMPs, and safety rules and regulations.
- Ensure associate are demonstrating proper aseptic behaviors and Good Documentation Practices on the Shop Floor. Provides innovative solutions to complex or process improvement issues.
- Support investigations and impact assessments for deviations.
- A self-motivated individual with a strong sense of ownership and discipline.

Essential Requirements:

- Bachelor's degree in a STEM field (Science, Technology, Engineering & Math) is preferred; If the applicant does not have a degree, 2 additional years of experience in pharmaceutical cGMP or aseptic environment is required beyond the below years
- 3+ years of relevant pharmaceutical experience
- 1+ years of experience on shop floor

OR:

- Bachelor's degree in a STEM field (Science, Technology, Engineering & Math) is preferred; If the applicant does not have a degree, 2 additional years of experience in pharmaceutical cGMP or aseptic environment is required beyond the below years
- 2+ years of Novartis RLT manufacturing experience

AND:

- Strong interpersonal, written, communication skills along with problem solving and follow-up skills are required.
- Must be well organized, flexible and work with minimal supervision.
- Knowledge of cGMP regulations and FDA guidance applicable to aseptic manufacturing
- Ability to lift or carry up to 35 pounds.
- Ability to gown aseptically and work in a clean room environment (Grade C) area for extended periods of time is required.
- 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.
- Previous Radio pharma experience a plus

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部门
Operations

Business Unit
Production / Manufacturing

地点
USA

状态
New Jersey

站点
Millburn

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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Production Lead

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