Production Manager

Job ID
REQ-10038673
Ene 30, 2025
Estados Unidos

Resumen

This role is located on-site in Carlsbad, CA. Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

At Advanced Accelerator Applications, a Novartis company, we are committed to leading innovation in nuclear medicine and delivering the next generation of targeted radioligand therapy (RLT) to cancer patients. We are looking for an experienced pharmaceutical manufacturing leader to help us reach our ambitious goals.

As the Production Manager for our new Carlsbad RLT Manufacturing site, you will be responsible for leading the manufacturing operations unit in achieving site objectives in areas such as Safety, Supply, Cost, Quality, and People for a GMP Facility.

About the Role

Key Responsibilities:

- Responsible for the daily operations and efficient utilization of resources to meet processing demands. Ensure products are produced, inspected, stored and released in accordance with approved procedures. Establish and maintain Production unit in full GMP and HSE compliance Support shop floor trouble shooting and problem solving as needed.
- Responsible for authoring, reviewing and/or approving GMP documents including but not limited to SOPs, Batch Records, Labels, Protocols, Reports, Validation documents. Ensure Good Documentation Practice are followed on the shop floor.
- Support compliance activities including deviations, CAPAs, Investigation and OOS and OOT Audit and review emergency paperwork and processes to ensure compliance. Perform analysis of trends in deviations and other events and facilitate resolution defining action plans.
- Monitor and regulate staffing needs to ensure optimum staffing levels are supporting business demands. Interview and hire production staff in conjunction with other functions and/or Head of Production.
- Establish and optimize training programs for manufacturing. Ensure production team receives complete cGMP training and are qualified to perform the required operations.
- Assist in preparation for commercial launch, including commissioning and qualification of rooms and equipment.
- Ensure and maintain qualified status of production equipment and methods for intended use in Production lines; Ensure adequate management of Production related validations, transfers, investigations related activities (deviations, OOS, OOE, OOT, CAPAs, trending), and Change Control systems.
- Prepare for and participate in Health Authority inspections and internal audits; Ensure Production

personnel are duly qualified, and manufacturing is properly conducted and documented for all performed activities; Evaluate and approve Production records as required and manage the staff objectives, performance, and development.
- Analyze Key Performance Indicators with a statistical mindset to identify opportunities for improvement. Implement cost control programs or procedures.
- Collaborate with supply chain organization to plan production and deliver 100% On-Time-In-Full deliveries.
- Follow-up on actions to ensure timely execution; Help promote an unbossed culture supporting ownership, innovation, speak-up, and accountability.

Essential Requirements:

- BS degree in life sciences, engineering, chemistry, biotechnology, or related field or equivalent relevant experience
- 4 or more years' experience in GMP operational roles with direct experience in pharmaceutical manufacturing, specifically low bioburden manufacturing preferred, 3+ years of leadership experience.
- Involvement with quality regulatory inspections of facilities from major agencies such as FDA or EMA.
- Strong change management skills, adaptability, and the ability to work under pressure.
- Good understanding of manufacturing and validation requirements and activities.

Desirable requirements:

- Training in radiochemistry, radio pharmacy and/or radiation safety
- Prior experience with low bioburden manufacturing

#LI-Onsite

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: novartis-life-handbook.pdf

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 $108,500 and $201,500 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.

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers who are focused on building and advancing a culture of inclusion that values and celebrates individual differences, uniqueness, backgrounds and perspectives. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to fostering a diverse and inclusive workplace that reflects the world around us and connects us to the patients, customers and communities we serve.

Accessibility & Reasonable Accommodations

The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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