NOVARTIS

# Production Manager

Job ID
REQ-10025567
Okt. 11, 2024
USA

## Zusammenfassung

#LI-Onsite

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 to cancer patients. We are looking for experienced Manufacturing and Quality Assurance professionals to help us reach our ambitious goals.

The Production Manager for Carlsbad RLT Manufacturing is responsible for leading the manufacturing operations unit in achieving site objectives in areas such as Safety, Supply, Cost, Quality, and People for a GMP Radioligand Therapies Production Facility. The leader will identify and implement the necessary programs and actions to ensure sustainable and reliable execution of manufacturing operations in alignment with cGMP regulatory expectations at the Carlsbad Site.

## About the Role

**Key Responsibilities:**

Responsibilities include but not are limited to:

- Responsible for the daily operations and efficient utilization of resources to meet processing demands.
- Ensure the 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.
- Ensure production team receives complete cGMP training and are qualified to perform the required operations.
- Support compliance activities including deviations, CAPAs, Investigation and OOS and OOT
- Interview and hire production staff in conjunction with other functions and/or Head of Production.
- Implement cost control programs or procedures.
- Audit and review emergency paperwork and processes to ensure compliance.
- Monitor and regulate staffing needs to ensure optimum staffing levels are supporting business demands.
- Establish and optimize training programs for manufacturing.

- 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.
- Collaborate with supply chain organization to plan production and deliver 100% On-Time-In-Full deliveries.
- Perform analysis of trends in deviations and other events and facilitate resolution defining action plans.
- Follow-up on actions to ensure timely execution; Help promote an unbossed culture supporting ownership, innovation, speak-up, and accountability.

**Job Dimensions:**

**Number of associates:**

Direct: 3-5 associates

**Financial responsibility:**

(Budget, cost, sales, etc.)

Manufacturing OPEX budgets.

Responsible for drug product COGS >US $1 million.

**Working Conditions**:

- Ensures reliable and compliant operations. Improves outcome in regulatory inspections.
- On-site with daily presence in a pharmaceutical laboratory and manufacturing facility.

**Essential Requirements:**

- BS degree in life sciences, engineering, chemistry, biotechnology, or related field or equivalent relevant experience
- Training in radiochemistry or radio pharmacy is an preferred
- 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.
- Shows the appropriate sense of urgency around given tasks
- Strong change management skills, adaptability, and the ability to work under pressure.
- Proficient technical writing skills.
- Proven ability to plan and manage operational process for maximum efficiency and
- Good understanding of manufacturing and validation requirements and activities.
- Radiation safety education (desired).
- Strong leadership skills (communication, cross-functional teamwork, drive to enable problem solving).
- Leverage new technologies and techniques to eliminate non-value adding activities and improve

productivity / performance through new processes.

**Commitment to Diversity & Inclusion:** Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve

**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

**Benefits and Rewards:** Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

**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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