# Manufacturing Operations Specialist

Job ID REQ-10060379

9月 02, 2025

**USA** 

### 摘要

Location: Morris Plains, NJ #LI-Onsite

Novartis is unable to offer relocation support for this role. Please only apply if the location is accessible for you.

Company will not sponsor visas for this position

#### About this role:

This role is responsible for working with the Manufacturing Operations team to complete all daily responsibilities for manufacturing support as well as aiding the oversight of all activities occurring in the manufacturing (Shopfloor) area on the 3rd shift to ensure quality and compliance, high performance and scheduled delivery.

Shifts(multiple positions):

- · Sunday Thursday 10 PM 6:30 AM
- · Tuesday Saturday 10 PM 6:30 AM
- · Friday Monday 8 PM 6:30 AM

#### About the Role

#### Key Responsibilities:

- Ensure accurate SAP inventories are maintained for all components and assist with monthly cycle counts
- Oversight of shopfloor area cleaning including aseptic Techniques, Clean room behaviors, and cleaning process.
- Oversight of planned activities in the shopfloor area to ensure compliance with area procedures and/or approved workplans.
- Setup materials for scheduled manufacturing processes
- Ability to gown aseptically and work in a clean room environment (ISO 8, areas for extended periods of time.
- Setup materials for scheduled manufacturing processes
- Perform review of logbook entries to ensure entries are accurate and legible.
- Aid in oversight of aseptic behaviors for all maintenance and cleaning activities on the shopfloor area
- Setup materials for scheduled manufacturing processes
- Equipment cleaning is performed as required
- Ensure proper status segregation, expiry, control, and storage of media lots and dispensary materials
- Ensure monthly safety and module walkthroughs are performed and follow up actions are addressed in a timely manner
- Documents all applicable steps in the relevant electronic systems and/or paper logs in line with GMP requirements.
- Qualified on proper aseptic techniques needed/applicable for the scope of this role.
- Plan and Perform proper environmental monitoring activities as needed.
- Perform review of logbook entries to ensure entries are accurate and legible.
- Proficient in the use of production related IT systems such as SAP, LIMS, MES.
- Execute MES activities to support Manufacturing Operations and Batch Record Review.
- Integrating and harmonizing best practices within your areas of expertise
- Role model Novartis's Values and Behaviors. Enforces best in class cGMP, cGLP, and aseptic behaviors.
- Support deviation investigations that involve work environment
- Support lifecycle management of area SOPs and GWIs
- Accountable for maintaining an audit ready work environment
- Accountable for initiation of work orders for required area maintenance.
- Responsible for cross departmental communication during planned and unplanned events to ensure manufacturing operations start on time and within compliance.
- Perform miscellaneous duties to support evolving business needs

#### **Essential Requirements**

 High School Diploma or GED equivalent with 2+ years aseptic cGMP experience with strong preference in Cell and Gene.

#### OR:

 Bachelor's degree in a relevant scientific discipline is preferred with a minimum of 1 year experience in cGMP or academic or lab setting with aseptic or cell culture experience.

#### AND:

- SAP/MES knowledge
- Strong interpersonal, written and communication skills along with problem solving and followup skills are required
- Environmental Monitoring and Aseptic experience preferred.
- Train the Trainer Certification
- Must be well organized, flexible, and work with minimal supervision
- Ability to lift up to 50 lbs.
- Alternate shifts, weekends and overtime will be required
- Requires handling of chemicals such as corrosives, solvents, and bio-hazardous materials

The salary for this position is expected to range between \$30.57 and \$56.82 per hour. The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors. Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards. US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

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? <a href="https://www.novartis.com/about/strategy/people-and-culture">https://www.novartis.com/about/strategy/people-and-culture</a>

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| Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <a href="https://www.novartis.com/careers/benefits-rewards">https://www.novartis.com/careers/benefits-rewards</a> |
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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 <a href="mailto-us.reasonableaccommodations@novartis.com">us.reasonableaccommodations@novartis.com</a> 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.

部门 Operations

Business Unit Universal Hierarchy Node

地点 USA

状态 New Jersey

站点 Morris Plains

Company / Legal Entity U014 (FCRS = US014) Novartis Pharmaceuticals Corporation Functional Area Technical Operations

Job Type Full time

Employment Type Regular

Shift Work No

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