Associate Director, Manufacturing Support

Job ID
REQ-10067957

12月 05, 2025

USA

摘要

The Associate Director, Manufacturing Support, is responsible for multiple functions within the site. These responsibilities include driving the manufacturing operational excellence project management portfolio for clinical and commercial manufacturing. Oversight of the critical environment cleaning program across the business. Contract management of gowning and manufacturing consumable services. Finance council representative for manufacturing operations. This position will also be responsible for the scheduling of manufacturing production activities and supporting the daily Tier processes. This role oversees the manufacturing training program and continuous improvement initiatives to ensure safe, compliant, and efficient operations.

About the Role

Location:

- This position will be located in Durham, NC and will be a fully on-site role.

- Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

Key Responsibilities:

- Leads internal and external strategy and planning meetings, surveys, new business presentations, mobilization, and support activities related to the environment cleaning program.
- Act as project lead for manufacturing support Op Ex projects and communicates project status, issues, assessing risks, and proposing solutions to the site leadership team.
- Second line of contact to all facilities cleaning, GMP & Non- GMP cleaning.
- Facilitation of Tier 2 meetings and attendance at Tier 3 meetings for Manufacturing.
- Financial responsibility for tracking spend, identifying accrual discrepancies, identifying credits, and providing monthly report commentary for manufacturing expense budget
- Lead development and management of detailed, task-based finite schedules to align multi-functional activities and ensure seamless execution across compounding, parts prep, filling, inspection, and assembly & packaging.
- Manage the daily and weekly scheduling meetings and serve as back-up finite scheduler.
- Oversight of the manufacturing training program.
- Ensure site cleaning and gowning programs in compliance with Novartis Standards to maintain site in compliant state for manufacturing GMP products.
- Develops and maintains compliant housekeeping program to ensure GMP manufacturing and testing facility is in compliant inspection ready state. Programs to include routine walkthrough of GMP warehouse, manufacturing, and test labs, to identify, track and resolve housekeeping deficiencies.
- Manages budget and staffing levels to ensure appropriate resources are available for both FTE and external service providers.
- Approves vendor invoices as needed and assist in developing and approving necessary service contracts.
- Manages inventory levels for both cleaning and gowning materials as well as supplier contracts or service contracts associated.
- Reviews and evaluates existing cleaning programs and services, makes recommendations to manufacturing operations team.
- Maintains compliant procedures and logbooks associated with cleaning activities.
- Supports investigations related to cleaning, gowning, or housekeeping.
- Performs or manages applicable area CAPAs, Quality Events, CR Actions, and other Quality non-conformances.
- Partners with Quality to address these issues effectively and compliantly.
- Coordinates daily operations with scheduling team to ensure cleaning activities align with manufacture and testing operations.
- Develop and report appropriate KPI for cleaning, gowning and housekeeping.
- Identifies and implements continuous improvement opportunities.
- Leads and mentor departmental staff.
- Writes performance reviews and annual goals, holds one-on-ones, and handle HR related matters Implement, train, and educate staff on the on-going efficient delivery, operation, and maintenance of the cleaning program.
- Other related duties as assigned.
- Perform other related duties as assigned.

Essential Requirements:

- B.S. degree in engineering or a related technical field; or equivalent industry experience.
- 10+ years of experience in GMP manufacturing operations
- Pharmaceutical/Biopharma Industry experience required
- Knowledge of FDA regulations and GMP systems; strong understanding of cGMP documentation and compliance practices.
- Excellent oral and written communication skills; strong technical writing ability required.
- Proven ability to mentor and develop staff; foster a culture of continuous improvement and operational excellence.
- 5+ years ' experience leading and managing teams.
- Project management skill set, including strategic/tactical planning, team building, risk management, and budget adherence.
- Prior experience conducting deviation investigations in a cGMP environment.

Work Environment & Physical Requirements:

- Fully On-site role supporting GMP manufacturing areas (compounding, parts preparation, cell expansion, upstream, downstream, filling, inspection, packaging); adherence to gowning and safety procedures required.
- Ability to work in controlled/cleanroom environments and coordinate across shifts to meet operational needs.
- May require off-hours support to meet production schedules and investigation timelines.

Novartis Compensation and Benefit Summary:

The salary for this position is expected to range between $132,300 - 245,700 annually.

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.

#LI-Onsite

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: 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. 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.

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.

部门
Operations

Business Unit
Production / Manufacturing

地点
USA

状态
North Carolina

站点
Durham

Company / Legal Entity
U473 (FCRS = US473) Novartis Gene Therapies

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work
No

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