Associate Director, Manufacturing Science & Technology - Drug Product

Job ID
REQ-10066082

11月 04, 2025

USA

摘要

The Associate Director, Manufacturing Science and Technology is responsible for leading the Manufacturing Science and Technology organization at a manufacturing site to ensure consistent and reliable production of drug products. This role involves oversight of process improvements, regulatory compliance, and technical leadership in the production environment.

About the Role

Location:

- This position will be located in Durham, NC and will be an onsite role.

Responsibilities:

- Monitor and improve manufacturing processes, including data and reports supporting regulatory compliance of drug products as they are processed through formulation and aseptic fill/finish.
- Define and direct staff activities to plan, execute, and document experiments, studies, and manufacturing processes that qualify key equipment, raw materials, and processes for clinical and commercial production.
- Provide ownership and management of process, analytical, and characterization knowledge related to drug product production and the raw materials required.
- Build and maintain a high-performing staff of engineers and scientists to support ongoing production and process transfers.
- Serve as a key scientific and technical representative for process-related issues at internal sites and with external partners.
- Partner with Manufacturing to meet production schedules, ensure commercial supply, and uphold quality standards.
- Partner with Regulatory to support product submission and approval processes.
- Perform trending and monitoring of critical quality attributes and process parameters to maintain product quality and control process drift.
- Identify and implement process improvements in collaboration with manufacturing operations.
- Review and provide feedback on project deliverables and offer technical/scientific support (e.g., remediation initiatives, reports).
- Lead investigations with Manufacturing, Quality, and other business units to determine root causes for variations, implement solutions, and ensure corrective actions are effective.
- Collaborate with other departments on manufacturing-related issues to resolve problems and support organizational goals.
- Own the process, plan to avoid delays, and lead activities to ensure a robust and effective product and manufacturing process.
- Perform other related duties as assigned.

Requirements:

- M.S. degree in biochemistry, chemical engineering, bioengineering, or a related technical field, with at least 8 years of experience in pharmaceutical manufacturing; or a B.S. degree with 10 years of experience in the same field.
- Excellent oral and written communication skills.
- Experience in senior laboratory or operational roles within a biopharmaceutical GMP manufacturing environment, including experience with formulation and aseptic fill/finish.
- Familiarity with global cGMP manufacturing regulations for aseptic fill/finish products and associated validation/qualification requirements.
- Strong technical knowledge of associated regulatory requirements.
- Proven ability to effectively lead and participate in teams.
- May require up to 25% travel.

Novartis Compensation and Benefit Summary:

The salary for this position is expected to range between $132,300.00 - $245,700.00 Annual.

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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