NOVARTIS

Manufacturing Unit Lead-Drug Substance

Job ID
REQ-10083243
Jul 22, 2026
LOC_US

About the Role

Key Responsibilities

- Lead Drug Substance manufacturing operations from facility start-up through commercial production. Serve as the process owner and end-user representative for Drug Substance (DS) manufacturing, process equipment, and systems throughout the project lifecycle.
- Provide technical leadership for manufacturing processes, equipment, validation, and operational readiness activities.
- Ensure safe, compliant, and reliable manufacturing operations aligned with cGMP requirements.
- Build, lead, coach, and develop a high-performing manufacturing team while maintaining training compliance.
- Drive inspection readiness and support successful regulatory inspections, audits, and compliance activities.
- Lead deviation investigations, root cause analysis, and implementation of effective Corrective and Preventive Actions.
- Champion operational excellence initiatives to enhance productivity, process robustness, and manufacturing performance.
- Explore and leverage data and technology to support the site's digital transformation journey.

Essential Requirements

- Bachelor’s degree in Engineering, Chemistry, Biology, Pharmacy, or related scientific discipline.
- Minimum 10 years of pharmaceutical or life sciences manufacturing experience in GMP environment.
- Minimum 5 years of people leadership experience managing manufacturing operations and developing high-performing teams.
- Demonstrated experience leading quality, compliance, inspection readiness, and regulatory audit activities.
- Strong knowledge of Drug Substance manufacturing processes, validation, qualification, and commercial operations.
- Proven ability to drive operational excellence, continuous improvement, and cross-functional collaboration in a regulated environment.

Desirable Requirements

- Experience with Active Pharmaceutical Ingredients (API), freeze drying (lyophilization), manufacturing skids, and oligonucleotide manufacturing.
- Lean Management, Operational Excellence certification, or comparable qualifications.

The salary for this position is expected to range between $138,600 and $257,400 per year. 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.

To learn more about the culture, rewards and benefits we offer our people clickhere.

#LI-Onsite

Role Requirements

Division
DIV_TO
Business Unit
Production / Manufacturing
Location
LOC_US
Site
Morrisville (North Carolina)
Company / Legal Entity
U473 (FCRS = US473) Novartis Innovative Technologies Inc
Functional Area
FCT_TO
Job Type
Full time
Employment Type
Regular
Shift Work
No
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