

Aseptic Drug Product MS&T Lead

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REQ-10082684
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США
Available in: English

Сводка

Imagine leading the science and technology that helps bring life-changing therapies to patients around the world. As the Aseptic Drug Product MS&T Lead, you will play a critical leadership role at our Durham site, driving manufacturing excellence across clinical and commercial aseptic drug product operations. You will lead a talented team of scientists and engineers, oversee process validation and continuous improvement initiatives, and partner across functions to ensure reliable, compliant, and efficient manufacturing. This is an opportunity to shape manufacturing strategy, influence product quality, and make a meaningful impact on patients while helping advance the future of healthcare at Novartis.

About the Role

Location:

- This position will be located in Durham, NC and will be an onsite role.
- Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

Key Responsibilities:

- Lead and optimize aseptic drug product manufacturing processes to ensure quality, compliance, and operational performance.
- Build, develop, and inspire a high-performing team of scientists and engineers.
- Drive technical transfers, process scale-up activities, and lifecycle process management.
- Oversee process validation, aseptic validation, Continued Process Verification, and supporting validation studies.
- Monitor manufacturing data, trends, and reports to maintain regulatory compliance and process robustness.
- Partner with Manufacturing to support production schedules and ensure reliable product supply.
- Serve as the technical lead for process-related challenges and scientific discussions with internal and external stakeholders.
- Collaborate with Regulatory Affairs to support product submissions and inspections.
- Lead cross-functional investigations, identify root causes, and implement effective corrective and preventive actions.
- Champion continuous improvement initiatives that enhance product quality, efficiency, and manufacturing excellence.

Essential Requirements:

- Bachelor of Science degree in Biochemistry, Chemical Engineering, Bioengineering, or a related technical field with at least 10 years of aseptic biopharmaceutical manufacturing experience, or a Master of Science degree in a relevant scientific or engineering discipline with at least 9 years of aseptic biopharmaceutical manufacturing experience.
- Proven experience leading and developing high-performing technical teams.
- Strong expertise in aseptic filling operations and pharmaceutical manufacturing processes.
- Demonstrated knowledge of process validation, aseptic validation, and Continued Process Verification activities.
- Understanding of global regulations governing pharmaceutical manufacturing, qualification, and validation requirements.
- Experience managing complex technical projects and cross-functional initiatives.
- Excellent written and verbal communication skills with the ability to influence diverse stakeholders.

Novartis Compensation and Benefit Summary:

The salary for this position is expected to range between \$138,600 and \$257,400 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: Learn about all the ways we'll help you thrive personally and professionally.
[Read our handbook \(PDF 30 MB\)](#)

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.

Дивизион
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Production / Manufacturing
Место
США
Состояние
North Carolina
Сайт
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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