Sterility Assurance Lead

Job ID
REQ-10046636

Apr 02, 2025

USA

Summary

This position will be located at Durham, NC and will not have the ability to be located remotely.

The Sterility Assurance Lead serves as the key functional expert for aseptic processing at the Durham, NC facility. The incumbent will be responsible for providing technical leadership, direction, and management of sterility assurance quality operations to support aseptic manufactured products. This includes the development and optimization of current processes and programs to ensure compliance with regulatory requirements, organizational development, and making appropriate decisions and recommendations to address trends, issues, or significant observations related to sterility assurance.
#LI-Onsite

Key Responsibilities:
- Provides leadership and oversight to Quality Operations aseptic oversight.
- Lead supervision of aseptic processing monitoring (Aseptic Process Simulation)
- Review, approve, and provide input to the Contamination Control Strategy for the site
- Provide quality assurance oversight/support of microbiological aspects related to manufacturing as environmental monitoring, gas/water monitoring and Bioburden monitoring.

- Lead and/or contribute to global aseptic projects including stakeholder management.
- Review, approve, and provide input and support of conceptual procedures in aseptic behavior and aseptic processes and ensuring their implementation as well as ensuring compliance with current regulatory requirements
- Supports development and implementation of contamination control strategies
- Provide oversight for product/process deviations, local and global escalations, change controls and audits/inspections, ensuring escalation and remediation of critical issues related to aseptic processes.
- Support root cause investigation and CAPA initiatives for microbiological contamination events/deviations
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- Provide QA oversight and support microbiological/aseptic best practices training program development and execution to foster culture of compliance and excellence
- Collaborate closely with site operations and quality to integrate comprehensive microbiological control measures site-wide

About the Role

Requirements:

- B.S. degree in scientific field preferably in Microbiology with 6 years ' experience in biopharmaceutical based GMP manufacturing operations including direct experience in managing sterility assurance programs for biotechnology manufacturing facilities or Master ' s Degree with 6 years ' experience in biopharmaceutical based GMP manufacturing operations including direct experience in managing sterility assurance programs for biotechnology manufacturing facilities
- Deep understanding of microbiology.
- Understanding of aseptic processes.
- Comprehensive knowledge of FDA and EMA regulations and experience in US and international regulatory agency inspections.
- Excellent verbal, written communication skills and the ability to interface with multiple areas within the organization is essential.
- Ability to synthesize data and summarize outcomes to provide recommendations on a compliant path forward for microbial contamination events.
- Demonstrated ability to perform long-term project planning, team building, budgeting and operational excellence.\
- The global nature of the job requires the position to have excellent knowledge of the various regulatory and GMP requirements as well as outstanding communication skills.
- Strong biotech background in cGMP Manufacturing of Drugs

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $132,300 and $245,700/year; ***however, while salary ranges are effective from 1/1/25 through 12/31/25, fluctuations in the job market may necessitate***

adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills, and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an "at-will position" and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

Company will not sponsor visas for this position.

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

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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:

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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.

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North Carolina

勤務地
Durham

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

Functional Area
Quality

職種
Full time

雇用形態
Regular

Shift Work

No

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