Sterility Assurance Lead, CGT

Job ID
REQ-10023263
Sep 27, 2024
USA

Summary

The Sterility Assurance Lead serves as the key functional expert for aseptic processing at the Morris Plains, NJ facility. The incumbent will be responsible for providing technical leadership, direction, and management of sterility assurance quality operations to support aseptic manufactured CGT (cell and gene therapy) 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.

About the Role

Location: This position must be located on-site in Morris Plains, NJ

Provides technical leadership and expertise in sterility assurance and microbial control, ensuring compliance with cGMP and regulatory requirements, supporting site readiness for inspections, leading contamination investigations, driving new technology implementation, and maintaining industry knowledge, while collaborating across functions and acting as a role model and talent sponsor.

- Collaborate with site operations, quality heads, Novartis representatives, and quality leaders to ensure comprehensive sterility assurance support across the site.
- Provide technical leadership for sterility process assurance and microbial control, ensuring compliance with cGMP and regulatory requirements.
- Offer expert advice and technical support to prepare sites for regulatory and internal inspections.
- Lead and support investigations into microbial contamination events, establishing root causes and CAPA.
- Assist the team in justifying microbial controls and limits for CGT products.
- Support the preparation and delivery of Validation Plans, Site Quality Risk Assessments, and Quality Assessments related to sterility assurance.
- Provide quality input into product- or process-related deviations, change control, and audits/inspections, ensuring proper escalation and remediation of critical issues. Participate in Site and Global Quality sterility assurance processes.
- Drive the implementation of new technologies for microbial monitoring and controls.
- Optimize and standardize aseptic techniques, cleaning and disinfection programs, microbiological monitoring, and sterilization techniques across network sites.
- Provide technical expertise for marketed and clinical products, representing the company in regulatory discussions and supporting regulatory audits and filings.
- Maintain up-to-date knowledge of industry technologies and regulations.
- Evaluate and anticipate the impact of emerging regulatory requirements in collaboration with QA and Regulatory business partners, integrating external expectations into Novartis Standards for Cell and

Gene Therapies.
- Interact with Operations, Quality, Commercial, Clients, and relevant technical support functions within Novartis and third-party manufacturers as needed.
- Support cross-site/platform and network projects.
- Sponsor potential talents to develop the talent pipeline.
- Act as a role model in accordance with Novartis Values and Behaviors and leadership standards.

Key Performance Indicators:

- Execution of responsibilities in a timely and efficient manner
- Successful Health Authority Inspections
- Number and severity of cGMP issues identified during internal and external audits / inspections related to aseptic processes
- Follow-up actions from Health Authority Inspections incl. Quality programs or GMP upgrades performed in time & cGMP-compliant

Job Dimensions:

Financial responsibility:

(Budget, cost, sales, etc.)

Understands economic business impacts of their decisions. Defining and implementing sterility assurance improvement measures

Impact on the organization:

High; significantly contributes to success of CGT and Morris Plains objectives by ensuring cGMP-Compliance with focus on Successful Health Authority Inspections & correct, cGMP compliant decisions as part of critical Quality Issues (e.g. market actions). Lack of leadership and wrong decisions could result in a negative financial impact (e.g. batch rejections) and a lack of reputation of the company due to Quality System Issues, major GMP-violations incl. at Risk Health Authority Inspections (worst case warning letters, launch delays, supply interruptions).

Ideal Background:

B.S. degree in scientific or technical 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

or PhD with 4 years' experience in biopharmaceutical based GMP manufacturing operations including direct experience in managing sterility assurance programs for biotechnology manufacturing facilities (Masters or PhD preferred).

- Deep 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 (cellular or gene therapies, proteins)
- Strong quality background in understanding of quality systems and regulatory requirements
- Ability to work under pressure, ability to assert oneself, fast decision making, high flexibility

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The pay range for this position at commencement of employment is expected to be between $97,600 and $146,400/year; however, while salary ranges are effective from 1/1/24 through 12/31/24, 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

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Handbook. https://www.novartis.com/careers/benefits-rewards

Commitment to Diversity and Inclusion:
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Join our Novartis Network:
If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here:
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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?
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