Aseptic Process Lead

Job ID
REQ-10049233

Apr 23, 2025

USA

Summary

The Aseptic Process Lead will act as SME for sterility assurance topics, supporting investigation and leading continuous improvement to improve aseptic processing.

About the Role

365 days a year, we aspire to be the best manufacturer of Cell & Gene therapies to ensure our patients have the treatments they need to live longer, healthier lives.

This role is located on-site in Morris Plains, NJ. Novartis is unable to offer relocation support for this role.

Major accountabilities:

Business Process & Improvements:

· Process lead and oversight, coordinates across multi disciplines, including QA, QC, Manufacturing Team (PU), MS&T, Development, Regulatory, Engineering, etc. for-Aseptic process improvements, material/equipment changes

· Provide timely updates to management on status of all GMP-related projects

· Work with regulatory department to ensure process related improvements are handled appropriately within regulatory framework and timelines

· Oversee and coordinate change controls for process and product-related changes

Technical Improvement Execution:

· Initiate and support the execution of improvement projects, liaising with all the relevant parties to ensure accurate execution.

· Author, review, and approve technical documents, SOP ' s, protocols, and reports to ensure accuracy

· Ensure protocols are executed as intended

· Author/support quality risk assessments

Deviations, Investigations, and CAPAs:

· Support/author investigations, Quality Events, CAPAs, and CAPA effectiveness checks related to process within required timelines

· Communicate and coordinate with other departments on deviations, investigations, quality events and CAPAs

· Ensures all CAPAs are implemented through GMP systems (e.g. MBR revision, training, etc.)

· Use process knowledge to analyze data to provide process understanding, and to identify root causes of product and process failures

Shop Floor Support:

· Provide front line technical and procedural support to manufacturing, working with the shift teams, focusing on manufacturing each batch safely, on time, in compliance with the batch instructions and quality requirements

· Leads decision making effort for aseptic process interventions

· Build technical knowledge and culture to empower associates to react appropriately to unplanned situations

Training:

· Support development of strong aseptic training

· Owns the Training Curriculum for this Job Profile and provides the necessary training and support to new associates

· Provide training for assigned new processes, technical document execution and products

Audit Support:

· Maintain their processes at inspection readiness level and to provide the necessary

support in any internal or external audit

The pay range for this position at commencement of employment is expected to be between $89,600 to $166,400/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.

Minimum Requirements:

· BSc. in Engineering, Pharmaceutical Technology, Chemistry, Pharmacy or equivalent scientific degree is required. MS degree is preferred.

· 3+ years of experience in aseptic GMP manufacturing role on the shop floor is required.

· Proven understanding of aseptic techniques and cell manufacturing (Pharma, GMP, Regulatory aspects) is required.

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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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Functional Area
Technical Operations

職種
Full time

雇用形態
Regular

Shift Work
No

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