Aseptic Process Expert

Job ID
REQ-10030688
Nov 25, 2024
USA

Summary

Act as Subject Matter Expert for manufacturing aseptic behaviors related to technical training and shopfloor behaviors. Supporting investigation and leading continuous improvement to improve aseptic processing and training within the manufacturing area.

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. Please note the shift for this role is Monday through Friday (9am - 5pm)

Major accountabilities:

Process & Improvements:

• Participate in cross functional aseptic governance and provide insight to aseptic behaviors within manufacturing

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

• Supports updates to and execution of Aseptic operator and process qualification

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

Training:

• Support development of strong aseptic training within the Manufacturing Unit

• Owns the Aseptic Training Curriculum and provides the necessary training and support to 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

Deviations, Investigations, and CAPAs:

• Support investigations, Quality Events, CAPAs, and CAPA effectiveness checks related to aseptic process within required timelines

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

The pay range for this position at commencement of employment is expected to be between $88,000 to $132,000 a 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.

Minimum Requirements:

- Bachelor's degree in Biology, Pharmaceutical Technology, Chemistry, Pharmacy or equivalent scientific degree.
- 3+ years of relevant experience in aseptic GMP manufacturing shop floor is required.
- Proven understanding of aseptic techniques and cell manufacturing (Pharma, GMP, Regulatory aspects).
- Previous GxP experience is required.
- Excellent communication and collaboration skills.

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

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Aseptic Process Expert

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