Senior Process Expert

Job ID
REQ-10046809
Apr 09, 2025
USA

Summary

The Senior Process Expert will provide team coordination and support and on process issues and investigations. To drive process excellence initiatives improving site quality and efficiency in compliance with cGMPs, SOPs and applicable guidelines and regulations.

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.

About the Role

Major Accountabilities:

Business Process & Improvements:

- Project lead and oversight, coordinates across multi disciplines, including Manufacturing Team (PU), MS&T, Development, Regulatory, Engineering, etc. for process improvements, material/equipment changes.
- Lead for identifying opportunities for process, operational, and quality improvements in conjunction with Manufacturing Team (PU) and Operational Excellence Program (OpEx).
- Provide oversight and support for Process Expert team on Corrective/Preventative Actions, Quality Events and continuous improvement projects.
- Work with regulatory department to ensure process related improvements are handled appropriately within regulatory framework and timelines. Engage with Process Expert team to develop team standardization initiatives and production of job-aid materials.
- Provide direct training support for Process Expert trainees ensuring development of capabilities in process triaging, investigation performance and inter-department communications.
- Oversee and coordinate change control for process and product-related changes.

Technical Improvement Execution:

- Own and drive Change Controls related to process improvements that support Manufacturing initiatives.
- Support the execution of improvement projects, liaising with all the relevant parties at shop floor to ensure accurate execution.
- Manage multiple investigational topics for technical oversight towards team support and audit readiness.
- Review and assure that protocols and report are technically correct.

- Ensure protocols are executed as intended.
- Execute process improvements, scale-up.
- Ensure that process technical batches generate sufficient process knowledge by thoroughly testing critical variables.

Deviations, Investigations, and CAPAs:

- Author high criticality investigations, CAPAs, and CAPA effectiveness checks related to process within required timelines.
- Communicate and coordinate with other departments, Technical Research & Development, Manufacturing Science & Technology, Training, Clinical, Commercial as examples, on deviations, investigations and CAPAs.
- Ensures all CAPAs are effectively implemented through GMP systems.
- Use process knowledge to analyze data to provide process understanding, and to identify root causes of product and process failures.

Shop Floor Support:

- Provide 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.
- Provides latest information regarding best practices, investigation findings, CAPAs, MST/TRD experiences to manufacturing SMEs.
- Leads decision making effort for typical process interventions as required.
- Build technical knowledge and culture to empower associates to react appropriately to unplanned situations.

Training:

- Develop and provide training (as immediate response to unexpected events and for technical document execution) to the Cell Processing team.
- Coach new investigators as part of the Investigator Certification Program.
- Maintain compliance with training requirements.

Audit Support:

- Maintain processes knowledge at inspection readiness level and to provide the necessary support in any internal or external audit.
- Maintain understanding of multiple assigned investigational topics for audit support.

The pay range for this position at commencement of employment is expected to be between $81,200 to $150,800/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. Desirable MSc. or equivalent experience.
- 3 years' experience in GMP manufacturing role on the shop floor.
- 2+ Years experience Investigation writing and Root cause analysis.
- Proven process understanding (Pharma, GMP, Regulatory aspects).
- 2+ years of deviation/root cause analysis experience.
- 2+ years of extended knowledge of CAR-T product.

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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