NOVARTIS

Manager, Process Experts

Job ID
REQ-10040974
Feb 19, 2025
USA

Summary

The Manager, Process Experts, for Morris Plains Cell and Gene Therapy leads the team responsible for shop floor support and deviations, investigations and CAPA operating over multiple shifts 24/7/365. Specifically, the Manager, Process Experts, provides direction, leadership and guidance to Process Experts who support continuous improvement and technical support to cell processing operations.

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:

People and Leadership

- Accountable for all aspects of staffing including recruiting talent, onboarding and training, performance management and strategic/succession planning for key roles
- Ensures adequate resources and cross training to meet the demands of a multi-product cell processing operation
- Maintains up to date job profiles for all team members
- Develops and maintains individual development plans for direct reports
- Champions a culture of Diversity & Inclusion, transparency, continuous improvement and recognition
- Embeds Patient and Customer centricity into team culture
- Provides visible leadership to all team members by providing coaching and support
- Empowers team members to react appropriately to unplanned situations, driving decision making to the appropriate levels
- Support teamwork, strong communication and motivation within and across teams
- Supports the operations site strategy and ensure tactics are aligned with strategy

Shop Floor Support

- Oversees front line technical support and procedural support to manufacturing
- Oversee real time batch trending for improved Manufacturing Success Rate (MSR)
- Deviations, Investigations and CAPA
- Collaborates with Quality Assurance and provides oversight of deviation management to ensure timely and compliant closure
- Establishing and reporting metrics and visual management tools for deviations, investigations and CAPA

and reporting to Management for review and action

Deviations, Investigations and CAPA

- Organizes and leads cross-functional investigation teams for critical and complex investigations, including owning escalations and external communications
- Business Process & Improvements
- Oversees process, operational, and quality improvements in conjunction with Manufacturing Team (PU) and Operational Excellence Team (OpEx).
- Provides updates to Site Management and Global Teams on critical deviations
- Contributes to site financial & business goals
- Maximize Quality and process improvements with a business owner mindset
- Minimize rejected patient lots and material write-offs
- Performs prioritization of core operations, continuous improvement projects in line with Morris Plains long term strategic plan

Technology Transfer

- Provide timely support for process technology transfer activities from clients/3rd parties
- Ensures knowledge transfer from MS&T into Process Expert Team

Training

- Owns the training curriculum for PE and Sr PE and ensures effectiveness and compliance to training requirements
- Owns the Investigator Certification Program (ICP)

Audit Support / Client Support

- Act as SME during audits preparing data and presenting to health authorities and leading audit responses
- Oversees strategy of audit responses and storyboards
- Internal and external client management during investigations

The pay range for this position at commencement of employment is expected to be between $108,500 to $201,500/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:

- Bachelor's Degree in Engineering, Pharmaceutical Technology, Chemistry, Pharmacy or equivalent scientific degree is required. Master's Degree is desired
- 5+ years of relevant experience in a GMP manufacturing role on the shop floor and/or QA/QC environment is required

- Proven process understanding (Pharma, GMP, Regulatory aspects)
- 4+ years of deviation/root cause analysis experience is preferred
- Direct management experience is highly desirable
- Project management, Lean, Operational Excellence, Product/Process Development or Regulatory experience is highly desirable

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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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.

Division
Operations
Business Unit
Innovative Medicines
Location
USA

State
New Jersey
Site
Morris Plains
Company / Legal Entity
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Full time
Employment Type
Regular
Shift Work
No
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