NOVARTIS

Director, Cell and Gene Therapy Analytical Operations

Job ID
REQ-10031374
Mar 05, 2025
USA

Summary

Position: Director, Cell and Gene Therapy Analytical Operations
Location: East Hanover, NJ, United States (On-site)
Join Our Vision: At Novartis, we are on a transformative journey in cell and gene therapy, pushing the boundaries of medical innovation. We are currently seeking an experienced and visionary Director to lead our Cell and Gene Therapy Analytical Operations Team. In this critical role, you will support both cell therapy and gene therapy clinical products and oversee the Bioanalytics, Microbiology, Instrument & GDLIMS, as well as the Raw Material, sample Management and Stability teams. Your expertise will play a crucial role in ensuring the quality and compliance of our cell and gene therapy products.
As the Director for Cell and Gene Therapy Analytical Operations, you will play a critical role in ensuring the quality and safety of our cell and gene products in the clinical phase. Reporting directly to the Head of Cell Therapy Analytical Development and Operations, you will provide strategic leadership and technical expertise to the Analytical Operations team. Through effective management and collaboration with cross-functional teams, you will establish and maintain robust quality control processes to meet regulatory requirements and support the company’s goals in advancing cell and gene therapy manufacturing.

About the Role

Key Responsibilities:

- Lead a large Cell and Gene Analytical Operations organization (~40 associates), providing guidance, mentorship, and strategic direction to ensure the successful execution of quality control activities.
- Develop and implement quality control strategies, systems, and procedures to support the development, manufacturing and release of clinical cell and gene therapy products in compliance with regulatory requirements.
- Oversee sub-team activities including routine testing, method qualification / validation / transfer, environmental monitoring, stability, new instrument onboarding and LIMS build.
- Ensure compliance with current Good Manufacturing Practices (cGMP), industry standards, and regulatory expectations for quality control operations.
- Collaborate closely with cross-functional teams, including Analytical Development, Pilot Plant Manufacturing, Technical Operations, Quality Assurance, Regulatory CMC, and Facility and Engineering to ensure effective coordination and alignment of quality control activities.
- Drive continuous improvement initiatives, identifying and implementing innovative technologies, process enhancements, and best practices to optimize efficiency and ensure product quality.
- Lead and manage investigations related to out-of-specification (OOS) and out-of-trend (OOT) results,

deviations, ensuring timeline resolution and implementation of appropriate corrective and preventative actions (CAPAs).
- Track metrics for invalid assays and lead the team to perform analytical method trending to ensure consistent quality and identify areas for optimization.
- Support regulatory agency inspections and audits, respond to any observations or findings, and drive the implementation of corrective actions.
- Ensure proper documentation practices and data integrity in compliance with regulatory expectations and company policies.
- Plan and manage departmental resource and budget.

Requirements:

- BS with a minimum of 15 years in biopharmaceutical industry.
- Minimum of 8 years' experience in quality control.
- Minimum of 5 years of experience in direct people management.
- In-depth knowledge in Cell and Gene product testing methods such as qPCR/dPCR/ddPCR, ELISA, NGS, flow cytometry, potency, liquid chromatograph and microbiology methods.
- Strong understanding of cGMP regulations, industry standards, and regulatory expectations for cell and gene therapy quality control.
- Demonstrated leadership experience, including managing, and developing high-performing teams.
- Excellent organizational skills, with the ability to prioritize and manage multiple projects simultaneously.
- Effective communication and interpersonal skills, with the ability to collaborate and influence cross-functional teams.

Desirable Requirements:

- Experience with electronic systems such as SAP, LIMS, and Quality Management Systems.

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? https://www.novartis.com/about/strategy/people-and-culture

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Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $176,400-$327,600/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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Innovative Medicines
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USA
State
New Jersey
Site
East Hanover
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Job Type
Full time
Employment Type
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Shift Work
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Director, Cell and Gene Therapy Analytical Operations

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