

Director, Cell Therapy Analytical Development Flow, Potency & Characterization

Job ID
REQ-10013808
Jul 17, 2024
USA

Summary

Internal Job Title: Director, Cell Therapy Analytical Development

Position is on-site in East Hanover, NJ
#LI-Onsite

About the role:

Novartis: Pioneering New Frontiers: At Novartis, we are driven by a bold mission – to innovate for patient benefit. In the Cell Therapy Analytical Development team, we are at the forefront of revolutionizing healthcare through cutting-edge cell therapies. We are seeking an exceptional individual to join our team as the Director of Cell Therapy Analytical Development, where your expertise and leadership will have a direct impact on improving patient lives.

Your Impact: As the Director of Cell Therapy Analytical Development, you will be at the helm of a team of talented scientists, leading the development of innovative analytical methods to empower our cell therapy programs. Your work will be instrumental in ensuring the safety, efficacy, and quality of our cell therapy products as they progress from early-stage research through clinical trials and ultimately, to the patients who need them.

About the Role

Key responsibilities:

- Lead and manage a team of scientists to design, develop, and qualify analytical methods for cell therapy products, including rapid potency methods, flow cytometry-based methods, and various product characterization methods (Nanostring, Seahorse, xCelligence, Aurora etc.). Ensure methods are robust, reliable, and fit-for-purpose to support batch release and comprehensive product characterization.
- Collaborate with cross-functional teams, including Process Development, Analytical Operations, Technical Operations, Quality, and Regulatory CMC, to support development activities and ensure analytical methods are appropriately filed and implemented in a GMP environment.
- Stay up to date with the latest scientific and technological advancements in the field of cell therapy analytics, evaluate new analytical approaches, and implement innovative methods to enhance analytical capabilities.
- Provide scientific and technical guidance to the team, ensuring high-quality and timely execution of analytical development activities in alignment with project goals.
- Develop team members through mentorship, coaching, and providing opportunities for professional

growth and development, fostering a culture of continuous learning and career advancement.

- Collaborate with external partners (vendors, CROs) to leverage external expertise and resources for the development of analytical methods.
- Drive data-driven decision-making by ensuring effective data management, analysis, and reporting, and support regulatory filings as required.
- Maintain a safe and compliant working environment by ensuring adherence to relevant safety guidelines, SOPs, and Development Quality Practices (DQP).
- Resource and budget management.

Requirements:

- PhD in Immunology, Cell Biology, Biochemistry, or related discipline is strongly preferred with at least 10 years of relevant experience in the biotechnology or pharmaceutical industry. Master's degree in Immunology, Cell Biology, Biochemistry, or related discipline in a scientific discipline can be considered with at least 15 years relevant experience in the biotechnology or pharmaceutical industry.
- Proven track record of leading and managing analytical development teams and projects in the field of cell and gene therapy and/or biologics.
- Minimum of 4 years of experience in direct people management.
- Technical expertise in cell therapy analytical methods, such as potency assays, flow cytometry-based assays, and product characterization assays.
- Experience in analytical method development, optimization, qualification, and transfer, in accordance with regulatory guidelines and industry standards.
- Knowledge of cell therapy product quality attributes, specifications, and stability.
- Excellent communication, presentation, and interpersonal skills, and the ability to work effectively in a matrix organization and with external partners.
- Strong problem-solving, critical thinking, and decision-making skills, and the ability to handle multiple tasks and prioritize effectively.
- Highly motivated, self-directed, and results-oriented, with a passion for innovation and excellence.

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?

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Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between \$192,000-\$288,000; *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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Division

Development

Business Unit

Innovative Medicines

Location

USA

Site

East Hanover

Company / Legal Entity

U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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EEO Statement :

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Major Accountabilities ~ Steigern Sie Ihr wettbewerbsfähiges Umsatzwachstum ~ Identifizierung und Priorisierung von Kunden mit hohem Potenzial durch Datenanalyse (HCPs und Stakeholder), die Verschreibungsentscheidungen beeinflussen ~ Steigern Sie die Vertriebsleistung durch die geschickte Orchestrierung positiver Kundenerlebnisse ~ Engagieren und Beziehungen aufbauen ~ Führen Sie wertorientierte Gespräche (persönlich und virtuell), um kritische Kundenherausforderungen,

Entscheidungstreiber, Schwachstellen und Chancen zu verstehen ~ Personalisieren und orchestrieren Sie Customer Engagement Journeys für HCPs,

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