NOVARTIS

Director of Product Sciences, Cell Therapy Analytical Development

Job ID
REQ-10028370
Nov 25, 2024
USA

Sommario

Position: Director of Product Sciences – Cell Therapy Analytical Development
Location: East Hanover, NJ, United States (On-Site)
LI #onsite
Novartis: Pioneering New Frontiers: At Novartis, our mission in Cell Therapy Analytical Development and Operations is to innovate for patient benefit. We are seeking an inspiring Director of Product Sciences to design, lead, and support implementation of analytical CMC strategies to de-risk and enable early-to-late clinical development and commercialization of groundbreaking Cell Therapy products.
Your Impact: As the Director of Product Sciences, you will lead cross functional teams and drive product understanding by extended characterization, your wealth of knowledge in Immunology, Process and Analytics. You will be instrumental in shaping our product characterization landscape, setting standards, and guiding our product portfolio's analytical strategies from inception to commercialization.

About the Role

Key responsibilities:

- Generate, incorporate, and commoditize product knowledge linking immunological first-principles, patient starting material characteristics, process performance, product quality, and patient clinical outcomes via correlative analysis and mechanistic studies to support and enable Targe Product Profile.
- Establish guidance and framework to standardize product characterization strategies. Assess and define attribute criticality (CQA vs non CQA), specification setting, and control strategy justification to enable patient access to safe and efficacious cell therapy products.
- Advance product pipeline through expended capabilities and innovation to enable continued product and process understanding, extended characterization of cell therapy product, process intermediates and starting materials to inform new cell therapy programs and improve manufacturing success.
- Serve as subject matter expert in T cell immunology, patient starting material and cell therapy product characteristics. Design extended /exploratory characterization assays to assess T cell lineage, cytokine and effector molecule secretion and intracellular production; proliferation, degranulation, and cytotoxicity; memory composition, differentiation, and exhaustion/anergic/activation status; chemokine/trafficking receptor expression; and polarization states.
- Collaborate with cross functional teams including Analytical Development, Process Development, Quality Control, Quality Assurance, Regulatory CMC, Biostatistics to drive pipeline cell therapy products forward.
- Drive data-driven decision-making by ensuring effective data management, analysis, and reporting, and support regulatory filings as required.

Requirements:

- Ph.D. in Immunology or a related field with 10 years of experience in understanding and characterizing the human immune system and cell products.
- A minimum of 5 years of industry experience in Cell Therapy CMC development is required.
- A minimum of 5 years of leadership skills, encompassing both direct and matrix management.
- Proven track record in early to late phase development, commercialization, and life cycle management of cell therapy products.
- Technical expertise in cell therapy process and product characterization, and correlative analysis.
- Extensive experience in regulatory filing requirements and addressing health authority questions.
- Exceptional communications, scientific writing, and presentation skills.

Desirable Requirements:

- Hands-on interest and experience in relevant analytical methods.
- Strong foundation and practical experience in statistics.

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 $192,00-$288,000/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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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.

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Director of Product Sciences, Cell Therapy Analytical Development

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List of links present in page

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