Director of Product Sciences, Cell Therapy Analytical Development

Job ID REQ-10028370 Nov 25, 2024 Estados Unidos

Resumen

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

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

Commitment to Diversity & Inclusion: The Novartis Group of Companies are Equal Opportunity Employers and take pride in maintaining a diverse environment. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, gender, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash their full potential.

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.*

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up:

https://talentnetwork.novartis.com/network

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers who are focused on building and advancing a culture of inclusion that values and celebrates individual differences, uniqueness, backgrounds and perspectives. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to fostering a diverse and inclusive workplace that reflects the world around us and connects us to the patients, customers and communities we serve.

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 <u>us.reasonableaccommodations@novartis.com</u> 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.

División

Development

Business Unit

Innovative Medicines

Ubicación

Estados Unidos

Sitio

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

Job ID

REQ-10028370

Director of Product Sciences, Cell Therapy Analytical Development

Apply to Job

Source URL: https://prod1.adacap.com/careers/career-search/job/details/req-10028370-director-product-sciences-cell-therapy-analytical-development

List of links present in page

- 1. https://www.novartis.com/about/strategy/people-and-culture
- 2. https://www.novartis.com/careers/benefits-rewards
- 3. https://talentnetwork.novartis.com/network
- 4. https://www.novartis.com/about/strategy/people-and-culture
- 5. https://talentnetwork.novartis.com/network
- 6. https://www.novartis.com/careers/benefits-rewards
- 7. mailto:us.reasonableaccommodations@novartis.com
- 8. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/East-Hanover/Director-of-Product-Sciences--Cell-Therapy-Analytical-Development_REQ-10028370-1
- 9. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/East-Hanover/Director-of-Product-Sciences--Cell-Therapy-Analytical-Development_REQ-10028370-1