Director Analytical Project Lead

Job ID
392112BR

9月 11, 2024

USA

摘要

Position is onsite in East Hanover, NJ
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 to lead our team of Analytical Projects Leads. In this critical role, you will orchestrate the Analytical CMC strategies for various stages of cell therapy products, significantly contributing to the development and commercialization of groundbreaking CAR-T therapies.
Your Impact: As the Director, you will helm the Cell Therapy Analytical Project Lead function, driving excellence in a team renowned for agility and high performance. You will be instrumental in shaping our analytical landscape, setting standards, and guiding our product portfolio ' s analytical strategies from inception to commercialization.

About the Role

Your responsibilities will include, but are not limited to:

- Lead and nurture a high-caliber team, fostering an environment that balances innovation with agility. Actively coach and develop direct reports, fostering a culture of growth and excellence.
- Establish and maintain standards of work, business processes and platform strategy. Strategize and oversee critical quality attributes assessments, control strategies, and comparability criteria setting for diverse products.
- Ensure seamlessly analytical strategy execution for all cell therapy products. Manage the timely development, qualification, and transfer of methods for GMP lot release and stability studies.
- Author and refine regulatory CMC packages, including analytical methods and specifications for IND and BLA filings. Develop strategies for addressing health authority inquiries.
- Innovate with next-generation analytical methods to expedite the release of T-ChargeTM products.
- Offer strategic insights across the analytical network, encompassing Cell Therapy, Gene Therapy and Biologics.
- Build and maintain robust relationships with key partners and stakeholders such as TO, NIBR, GDD, Quality and RA CMC.

Role Requirements:

- BS with 15+ years, MS with 12+ years, or Ph.D. with 10+ years of analytical experience in biotechnology/pharmaceutical industry. Cell Therapy experience highly desired; Biologics experience also considered.
- A minimum of 5 years of leadership skills, encompassing both direct and matrix management.
- Proven track record in late phase development, commercialization, and life cycle management of biologic/cell therapy products.
- Extensive experience in regulatory filing and addressing health authority questions.
- Exceptional communications, scientific writing, and presentation skills.

Desirable Capabilities:

- 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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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 $192,000-$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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EEO Statement:

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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.

部门
Development

Business Unit
Innovative Medicines

地点
USA

站点
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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