NOVARTIS

Associate Director, Gene Therapy Analytical Development Chemistry

Job ID
REQ-10015304
Juli 17, 2024
USA

Zusammenfassung

#LI- Onsite Location is East Hanover, New Jersey As a key member of the Analytical Development leadership team, this individual and his/her team will be accountable for analytical development activities for current and future programs including/not limited to product characterization, assay development/optimization, technology transfers (internal and external), testing support, investigation, and development of source documents for regulatory filings. Deep expertise in analytical development for gene therapies is essential. Growth mentality, scientific curiosity, passion to serve patients, and dedication to staff development and cultivating an open, collaborating culture are critical for the success of this role. Demonstrated people leadership is a must.

About the Role

Major responsibilities:

- Provide strategic, technical and scientific leadership to the gene therapy analytical development bioassay team, to develop, optimize, and characterize robust analytical methods and new technology evaluation and implementation.
- Understand and characterize product critical quality attributes and develop assays to monitor and control these attributes
- Collaborate closely with peer function teams and communicate complex technical topics and decisions within the department and to program teams. Provide effective technical and business leadership at the R&D-CMC interface.
- Ensure seamless transition of analytical capabilities from development to a GMP laboratory.
- Work collaboratively with process development leadership to develop and/or analytical platforms to support company’s multi-product portfolio of development programs.
- Provide strategic leadership and influence for the development and tech transfer of analytical methods to support manufacturing of gene therapy products across a network of internal and external manufacturing sites.
- Develop, lead and coach a group of engineers/scientists through direct supervision and/or as matrix leader.
- Author and review regulatory submissions and responses to questions from health authorities.

Essential Requirements:

- PhD or equivalent in Biology, Chemistry, Biophysics, Biochemistry, Bioengineering or related scientific discipline.
- Minimum 5 years of relevant industry experience in analytical development for biological, preferably cell and gene therapy products is required.
- Strong fundamental knowledge of chromatography, protein/nucleotide biochemistry, cell biology, virology, immunology and existing analytical technology is expected. Proven track record in utilization of special tools/equipment, lab automation tools and specialized facilities.
- Demonstrated experience leading analytical development initiatives in support of cell or gene therapies, or protein biologics manufacturing, early- and late-stage.
- Proficiency in strategic planning, team dynamic management, and technical leadership.
- Proven leadership experience and strong people management skills with the desire and ability to deliver on objectives while developing people in a fast-paced environment.
- Expertise in high-performance liquid chromatography and physicochemical properties tests (UPLC, CE-SDS, AUC, DLS, SEC-MALS, particle analysis, cIEF, etc.), methods development, drug substance and drug product. Mass Spectrometry experience is a plus.
- Demonstrated ability to influence scientific and business strategies and decisions via collaboration, communication, team building, creative thinking, and strong organizational skills are required.

The pay range for this position at commencement of employment is expected to be between $158,400 & $237,600/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.

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.

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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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Employment Type
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No
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