

Senior Expert, Gene Therapy Analytical Development Chemistry

Job ID
REQ-10063959

10月 09, 2025

USA

摘要

As a key member of the Analytical Development team, this individual will support developmental activities to aid in delivering gene therapy to patients. The successful candidate will support technical and development projects designed to characterize gene therapy products through an assortment of analytical methods. This role will also contribute to cross-functional activities including monitoring and characterizing of processes and products to identify opportunities for continuous improvement. Growth mentality and passion to serve patients, his/her technical team and development programs is a must.

About the Role

#LI-Onsite

Key Responsibilities:

- Contribute to all project/network strategy and drive the implementation; apply scientific/technical/ GMP and/or quality-related expertise to address complex technical issues within a multifunctional project team.
- Coach team members and contribute to global technical strategies and goals; maintain and qualify equipment/infrastructure and manage operational aspects in lab as assigned.
- Design, plan, perform, interpret and report scientific experiments or testing for the preparation and timely delivery of drug substances (DS), drug products (DP), processes or procedures.
- Design, plan, and perform product characterization studies using chromatography (HPLC), Capillary electrophoresis (CE), mass spectrometry (MS) based and other biophysical/biochemical assays for the characterization and lot release/stability monitoring of gene therapy products. Identify, develop, validate and implement novel analytical assays and new GMP-compliant methodologies for pipeline gene therapy products
- Drive project timelines and deliverables while meeting internal quality and data integrity requirements
- Implement resolution to technical challenges, communicate effectively and present complex data within the department and cross-functionally
- Author and/or review method development reports, SOPs, validation reports and technical documents for regulatory filings
- Actively contribute to analytical development for clinical and commercial manufacturing and assist in advancing science-driven and innovative methodologies
- Independently identify new scientific technologies and instrumentation with the potential to improve development workflows. Actively keep ahead of the latest advances in analytical technologies for cell and gene therapy
- Work according to appropriate GMP/GLP regulations and Novartis SOPs/Guidelines and Code of Conduct

Essential Requirements:

- Bachelor's degree in Analytical Chemistry, Biology, Biochemistry, Molecular Biology, Immunology or related scientific discipline with > 4 years of prior experience in industry required. BS with > 5 years, MS with > 4 years and Ph.D. with > 3 years experience preferred
- state-of-the-art principles and theories in analytical chemistry, protein chemistry, nucleotide chemistry and related disciplines
- Strong scientific background and understanding of gene therapy, cell biology and drug product development
- Strong working knowledge on analytical software including but not limited to Chromeleon,

Empower, Chemstation, Astra, 32Karat, Xcalibur, Mascot, Byonic.

- Demonstrated ability to work collaboratively in a fast-paced team environment and quickly acquire new technical skills and knowledge
- Drives innovation by researching relevant literature to improve existing methodologies while evaluating alternative approaches
- Excellent organizational, communication and scientific/technical writing skills
- Facilitates the incorporation of ideas from conferences or literature into work processes

Desirable Requirements:

- Experience working with AAV, LVV analytics preferred.
- Experience with IND/BLA dossier authoring, response to agency questions is a plus

The salary for this position is expected to range between \$114,100 and \$211,900 per year.

The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors.

Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards.

US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

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. 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.

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

状态 New Jersey

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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