

# Associate Director, Gene Therapy Analytical Development Molecular Biology

Job ID  
REQ-10015306  
Jul 23, 2024  
USA

## Summary

#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 accountabilities:

- 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 Molecular Biology, Biochemistry, Virology, 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 molecular biology, biochemistry, virology, vectorology, and existing analytical technology (esp. next generation sequencing) is expected. Proven track record in utilization of special tools/equipment, lab automation tools and specialized facilities.
- Established experience with analytical method development and validation for state-of-the-art principles and theories in molecular biology analytical methods such as DNA/RNA isolation, primer design, end point PCR, qPCR, RT-PCR, digital PCR, Sanger sequencing, and next-generation sequencing (NGS)
- Expertise in molecular based gene therapy analytical methods and sequence analysis softwares such as Geneious, Applied Biosystems 7500, QuantaSoft
- Experience with bioinformatics programming (e.g., Python, R, etc.), is a plus
- Experience with analytical and/or statistical software (e.g., JMP, Softmax Pro, XLfit, Gen5 etc.), is highly beneficial
- 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.
- 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 \$166,400 and \$249,600/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.

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Division

Development

Business Unit

Innovative Medicines

Location

USA

Site

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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Major Accountabilities ~ Steigern Sie Ihr wettbewerbsfähiges Umsatzwachstum ~ Identifizierung und Priorisierung von Kunden mit hohem Potenzial durch Datenanalyse (HCPs und Stakeholder), die Verschreibungsentscheidungen beeinflussen ~ Steigern Sie die Vertriebsleistung durch die geschickte Orchestrierung positiver Kundenerlebnisse ~ Engagieren und Beziehungen aufbauen ~ Führen Sie wertorientierte Gespräche (persönlich und virtuell), um kritische Kundenherausforderungen, Entscheidungstreiber, Schwachstellen und Chancen zu verstehen ~ Personalisieren und orchestrieren Sie Customer Engagement Journeys für HCPs,

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