NOVARTIS

Expert/Senior Expert Science & Technology - Molecular Biology

Job ID
REQ-10015313
Jul 17, 2024
USA

Summary

#LI-Onsite. Located in East Hanover, New Jersey 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

Major accountabilities:

- Contribute to all project/network strategy and drive the implementation; apply scientific/technical/ GMP and/or quality-related expertise to address complex R&D 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 GMP testing or pilot plant processes for the preparation and timely delivery of drug substances (DS), drug products (DP), processes or procedures.
- Design, plan, and perform product characterization studies using molecular assays (i.e. NGS, qPCR, ddPCR and/or other molecular assay platforms) for DNA characteristics such as genomic integrity and residual packaged impurity DNA, 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

- Participates in activities such as RNA isolation, cDNA library construction, library amplification, genomic DNA isolation, polymerase chain reaction, and other standard molecular biology techniques.
- 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.
- Other related job duties as assigned.

Requirements:

The level of the role is commensurate to experience/education. Senior Expert level:

- Bachelor's degree in 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
- 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, qRT-PCR, droplet digital PCR, Sanger sequencing, next-generation sequencing (NGS)
- Experience in various molecular biology and sequence analysis softwares such as Geneious, Applied Biosystems 7500, QuantaSoft
- Strong scientific background and understanding of gene therapy, cell biology and drug product development
- Demonstrated ability to work collaboratively in a fast-paced team environment and quickly acquire new technical skills and knowledge
- 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 proficiency in developing and optimizing molecular bioassays independently with limited guidance
- 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
- Experience working with AAV, LVV analytics preferred. Familiarity with virology is a plus.

Expert

- Bachelor's degree in Analytical Chemistry, Biology, Biochemistry, Molecular Biology, Immunology or related scientific discipline with > 2 years of prior industry experience required.
- BS with > 5 years, MS with >2 years, Ph.D. with >1 year experience preferred
- Strong understanding and working knowledge of Cell Biology, protein, and DNA chemistry.
- Strong understanding and working experience with chromatography (HPLC), Capillary electrophoresis (CE), mass spectrometry (MS) based and other biophysical assays
- Working knowledge on analytical software including but not limited to Chromeleon, Empower, Chemstation, Astra, 32Karat, Xcalibur, Mascot, and Byonic a plus.
- Quick learner, highly motivated, hard-working and detail oriented.
- Strong ability to work in a fast-paced team environment with highly goal-oriented approaches and to prioritize work from multiple projects with can-do attitude is required
- Excellent written and verbal communication skills.
- Established ability to work in a regulated environment.
- Good presentation skills and scientific/technical writing skills Experience working with AAV, LVV analytics preferred.

The pay range for this position at commencement of employment is expected to be between $102,400 - 153,600 for Expert & $124,000 - 186,000 for Senior Expert /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

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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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Business Unit
Innovative Medicines
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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
Apply to Job
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