Expert Science and Technology - Gene Therapy Analytical Development - Chemistry

Job ID
REQ-10015309

12月 09, 2024

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 chromatographic and biophysical-based 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, their technical team and development programs is a must.

About the Role

Key Responsibilities:

- 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 chromatography (HPLC), Capillary electrophoresis (CE), mass spectrometry (MS) based and other biophysical 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 > 3 years and Ph.D. with 0-2 years experience preferred
- State-of-the-art principles and theories in analytical chemistry, protein chemistry, DNA 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 and experience working with AAV, LVV analytics preferred
- Facilitates the incorporation of ideas from conferences or literature into work processes
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The pay range for this position at commencement of employment is expected to be between

$102,400 - 153,600/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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Innovative Medicines

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U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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