

Senior Expert Science & Technology - Mass Spectrometry - Gene Therapy Analytical Development - Chemistry

Job ID REQ-10026834

10月 31, 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 with a technical focus on leveraging mass spectrometry.

This role will leverage deep Mass Spectrometry expertise to contribute to cross-functional activities including monitoring and characterizing of processes and products as well as to identify opportunities for continuous improvement. Growth mentality and passion to serve patients, technical teams, and development programs is a must.

About the Role

Your Responsibilities Include, but are not limited to:

- Design, plan, and perform product characterization studies utilizing a deep understanding of protein mass spectrometry. This includes optimizing and implementing experimental and routine analyses using methodologies like; peptide mapping for PTM determination, intact and middle down MS for variant identification, and quantitative methods such as TMT labeling and label-free quantitation
- Competitive candidates will also have a working understanding of chromatography (HPLC), capillary electrophoresis (CE), and other biophysical assays for the characterization and lot release/stability monitoring of gene therapy products.
- 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.
- 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

What you will bring to the role:

- Bachelor's degree in Analytical Chemistry, Biology, Biochemistry, Molecular Biology, Immunology or related scientific discipline with > 5 years of prior experience in industry required. BS with > 6 years, MS with > 4 years and Ph.D. with > 2 years experience preferred (Ph.D. preferred).
- State-of-the-art principles and theories in protein mass spectrometry, analytical chemistry, protein chemistry, DNA chemistry, and related disciplines. Experience working with AAV, LVV analytics preferred.
- Experience utilizing high-resolution MS is required, experience with Thermo Tribrid MS instrument highly valued
- Strong working knowledge on analytical software including but not limited to Byos, Proteome Discoverer, BioPharmaFinder, and Xcalibur, as well as basic understanding of Chromeleon, Empower, Chemstation, and 32Karat for chromatographic systems
- 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

The pay range for this position at commencement of employment is expected to be between \$124,000 - \$186, 000/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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部门 Development

Business Unit Innovative Medicines

地点 USA

站点 East Hanover

Company / Legal Entity U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

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Shift Work No

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