

Expert/Senior Expert - Potency

Job ID
REQ-10032287
Dec 04, 2024
USA

Summary

About the Role:

As a key member of the Analytical Development team, this individual will support developmental activities to aid in delivering cell and gene therapy to patients. The successful candidate will support technical and development projects designed to characterize cell and 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

This is a dual level posting for multiple openings. Job title will be Expert or Senior Expert, commensurate with experience and education.

Key Responsibilities:

- Performs a wide variety of laboratory tasks and experiments to collaboratively meet established timelines while maintaining high quality and data integrity.
- Provides detailed observations, analyze data and interpret results.
- Authors experimental reports, summaries and protocols.
- Reviews and approves data generated by other team members.
- Develops, optimizes, and leads qualification of bioassays suitable for gene therapy characterization, lot release and stability monitoring, may participate in assay transfer to QC department and/or external CRO.
- Continuously identified areas of improvement to ensure effective laboratory operations.
- Performs analytical testing including relative potency assay, protein expression assay, flow cytometry, cell count, cell viability, qPCR/dPCR, etc.
- Support tracking and trending systems, and programs, which assist in the testing, evaluation and monitoring of quality and efficiency.
- Assist in drafting and reviewing technical and regulatory documents to ensure completeness, accuracy, consistency and clarity. Present results and project updates to team

- Work according to appropriate GMP/GLP regulations and Novartis SOPs/Guidelines and Code of Conduct.

Essential Requirements:

- Bachelor's degree in 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 cell-based bioassays and other plate-based assays using variety of platforms including ELISA, flow cytometry, PCR, MSD, high-content imaging, and luminescent/fluorescent plate reader.
- Quick learner, highly motivated, hard-working and detail oriented.
- Expertise with aseptic technique and mammalian cell culture.
- 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.

Desired Requirements:

- 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 and LVV analytics preferred.

Senior Expert:

- Bachelor's degree in 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 Bioassay and related discipline. 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 Softmax Pro, PLA, JMP DoE..
- 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
- Work with junior research associate on experimental design, troubleshooting, assay optimization and data interpretation as needed.
- Demonstrated success and experience in plate-based bioassays using variety of platforms including but not limited to ELISA, MSD, high-content imaging and luminescent/fluorescent plate reader.

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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Division

Development

Business Unit

Innovative Medicines

Location

USA

State

New Jersey

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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