Gene Therapy Drug Substance Product Leader

Job ID
REQ-10051788

5月 12, 2025

USA

摘要

Internal job title: Senior Expert, Science & Technology

In this vital role, the Senior Expert, Drug Substance - Product Leader will be responsible for leading early through late-stage drug substance development of the Novartis Adeno-associated virus (AAV) and Lentivirus gene therapy programs. This role provides program leadership and supports the advancement of gene therapy programs through drug substance design and generating CMC strategies to meet product and program requirements.

This position will be located at Durham, NC and will not have the ability to be located remotely. This position will require up to 10% travel as defined by the business (domestic and/ or international).
#LI-Hybrid

About the Role

Key Responsibilities

- Lead early through late-stage development of the Novartis Adeno-associated virus (AAV) and Lentivirus gene therapy programs
- Lead and coordinate the drug substance development team and represent the drug substance process discipline in the global CMC project team of assigned programs
- Accountable for managing all drug substance development activities including process development, tech transfer, GMP manufacturing technical support, etc.
- Communicate effectively across organizational interfaces i.e. program-management, technical line functions, regulatory, quality, senior management, etc.
- Proactively identify scientific, technological and strategic risks, propose creative solutions and communicate key risk, issues, and progress to leadership and stakeholders
- Responsible for high quality drug substance process documentation for health authority submissions and interactions; act as technical expert in audits, inspections, etc.
- Develop, mentor and coach other scientific associates; present scientific /technical results internally and contribute to publications, presentations and patents; actively foster knowledge exchange.

Role Requirements:

- Bachelors' degree in relevant scientific field and 5 years of relevant industry experience
- 3+ years' relevant large molecule CMC development experience
- Previous experience in drug substance development; prior experience in adeno-associated virus and/or lentivirus gene therapy process development preferred
- Strong working knowledge of regulatory CMC expectations with significant experience with IND/BLA submissions
- Strong understanding of the drug development process, in depth knowledge of the strategic and operational aspects of the rare/orphan disease and gene therapy space preferred
- Proven leader that can effectively operate in a cross-functional, matrix environment and successfully manage multiple programs / priorities simultaneously
- Ability to provide strategic guidance to CMC development activities for gene therapy programs and also provide tactical support (i.e. technical expertise, project management, etc) to drive programs forward
- Potential of up to 10% travel

Preferred Qualifications:

- Advanced degree in relevant scientific degree

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $114,100 - $211,900/year; however, while salary ranges are effective from 1/1/25 through 12/31/25, 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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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

地点
USA

状态
North Carolina

站点
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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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REQ-10051788

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