Drug Product/Product Leader

Job ID
REQ-10042100
Mar 21, 2025
USA

Summary

Onsite: Durham, NC

Position Location: The ideal location for this role is our Durham, NC site, but remote work may be possible (there may be some restrictions based on legal entity). Please note that this role would not provide relocation as a result. If associate is remote, all home office expenses and any travel/lodging to the Durham, NC site for periodic live meetings will be at the employee's expense. The expectation of working hours and travel (domestic and/or international) will be defined by the hiring manager.

In this vital role, the Senior Expert, Drug Product – Product Leader will be responsible for leading early through late-stage 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 product design and generating development strategies to meet product and program requirements.

If this sounds like your next challenge, apply now!

About the Role

Internal job title: Senior Expert, Science & Technology

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 product asset development team and represent the drug product process discipline in the global CMC project team of assigned programs
- Accountable for managing all drug product development activities including process development, tech transfer, GMP manufacturing technical support, etc.
- Communicate effectively across organizational interfaces i.e. project-management, line functions, senior management, etc.
- Proactively identify scientific, technological and strategic risks, propose creative solutions and communicate key issues to the appropriate management level
- Responsible for high quality drug product process registration documents 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.

Minimum 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 product process 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% domestic travel

Preferred Qualifications:

- Advanced degree in relevant scientific degree

Why Novartis: Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between **$114,000 - $211,400**/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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status.

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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State
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Site
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Drug Product/Product Leader

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