

Associate Director, Drug Product Development

Job ID
REQ-10015290
Lug 12, 2024
USA

Sommario

Location: Durham, NC The Associate Director, Drug Product Development is responsible for the execution and management of formulation and drug delivery device related activities in Gene Therapy at Novartis. Gene Therapies are a fast growing and exciting area of next generation medicines where our knowledge and impact are advancing rapidly. Our team has a large pipeline of innovative viral vector therapies and needs top talent to join our effort to develop molecules for clinical use to improve outcomes for many of our patients. We are looking for a candidate that seeks collaboration with their peers, values teamwork and can thrive in a multisite/multidisciplinary team of highly effective and focused scientists.

About the Role

Your Key Responsibilities:

- Serving as a key scientific and technical representative for drug product team at internal sites, meetings and with external partners.
- Leads a diverse team of drug product scientists in the technical R&D laboratory to build capabilities for laboratory scale and early phase clinical scale for drug product formulations.
- Builds and maintains a high performing staff of engineers and scientists to support ongoing process and pipeline development as well as process transfers to internal and external manufacturing sites.
- Work cross-functionally to obtain feedback and alignment regarding projects and potential modifications to current DP manufacturing processes.
- Supports and develops new platforms to support complex formulations and drug delivery strategies for new and novel therapeutic modalities.
- Partners with Clinical, Manufacturing and Research to assure developability and manufacturability of clinical and commercial formulations.
- Partners with Regulatory and program leads to support submissions and approval of product applications.
- Reviews and provides feedback and technical/scientific support on project deliverables, (e.g. remediation initiatives, plan reports). Ensures all documentation and reports are accurate, complete, and suitable for using in support of development, characterization, and regulatory approval of products.
- Partners with Project Managers, Strategy Teams, Engineering, Supply Chain, and others to anticipate and plan for budget and capex cycles, human and materials resourcing.

Role Requirements:

- Bachelor's degree in Biology, Biochemistry, Chemical engineering, Bioengineering, Pharmaceutical Sciences, or related technical field. Master's degree/PhD preferred.
- 5+ years of Industry or equivalent experience in biologic drug development

- Leadership experience with proven ability to effectively lead and participate on teams.
- Excellent oral and written communication skills; attention to detail.
- Expertise in developing parenteral drug product manufacturing process technologies, including protein, viral or cell therapeutics.
- Deep understanding of principles and analytical techniques necessary to characterize biophysical and biochemical properties of viral vectors (AAV and LVV).
- Familiar with global health authority regulations, regulatory filings, validation/qualification requirements.
- Strong organizational skills and ability to multitask across projects and activities.
- Up to 10% travel required at times.
- Experience with viral vector (AAV and LVV) drug development highly desirable

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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Commitment to Diversity & Inclusion: The Novartis Group of Companies are Equal Opportunity Employers and take pride in maintaining a diverse environment. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, gender, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash their full potential.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between \$166,400- \$249,600/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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The Novartis Group of Companies are Equal Opportunity Employers and take pride in maintaining a diverse environment. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, gender, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash their full potential.

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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