NOVARTIS

Senior Expert Science & Technology, Process Development

Job ID
REQ-10025515
Nov 13, 2024
USA

About the Role

Your responsibilities include, but are not limited to:

- Lead and support projects within the research and development drug product laboratory to enhance manufacturing cell and gene therapy technologies, capabilities, and processes to advance pipeline programs
- Independently plan, design, and perform cell and gene therapy drug product formulation and process development studies supporting pre-clinical, clinical, and commercial operations
- Safely and compliantly execute lab operations for drug product process development studies, depending on job specific assignment. Collaborate with cross-functional groups to coordinate studies
- Lead and support tech transfer of new products, technologies, and processes to ensure smooth transition from process development into GMP manufacturing
- Evaluate and summarize data using analytical methodologies, interpreting results, drawing conclusions, and recommending options for future experiments to achieve project goals
- Independently author technical documents (SOPs, protocols, basic scientific reports) and presents results of development studies both internally and externally in a cross functional setting
- Provide support for regulatory filings
- Advance drug product process innovations as a technical lead through cross-functional collaboration teams across Novartis sites and organizations
- Leverages strong understanding of AAV and LVV drug product fundamentals to evaluate and introduce new technologies and innovative ideas related to drug product formulation and process development

What you'll bring to the role:

Requirements:

- Bachelors in biological sciences, pharmaceutical sciences, bioengineering, chemical engineering or related technical field with 6 years relevant experience; Masters with 4 years of experience, or PhD with 2 years of experience.
- Comprehensive experience with a variety of drug product process development experience such as formulation development, sterile filtration, container closure integrity testing (CCIT), aseptic fill-finish, and drug delivery
- Good knowledge or experience of laboratory skills and technical tools
- Ability to motivate peers and staff, foster an innovative and collaborative culture of continuous improvement and operational excellence
- Provide technical/scientific support in process development and qualification efforts in pre-clinical and

clinical manufacturing through laboratory studies designed to illuminate fundamental process and product performance (e.g. NOR & PAR setting, CPP edge of failure, CQA performance)
- Ability to effectively and efficiently analyze and interpret data to further progress development strategies.
- Excellent oral and written communication skills with project management experience. Strong technical writing ability required

Desired Requirements:

- Experience with 3rd parties (equipment vendors, and contract manufacturing insourcing/outsourcing) is preferred
- Working knowledge and experience with Design of Experiments (DoE) is preferred
- Working knowledge of FDA regulations and GMP systems is preferred
- Knowledge of viral gene therapy and previous experience with adeno-associated virus (AAV) and/or lentiviral vectors (LVV) formulation and process development is preferred

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

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

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 $124,000-$186,000; 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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Role Requirements

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