

Scientist, Upstream/Cell Culture

Job ID
REQ-10065927

11月 05, 2025

USA

摘要

#LI-onsite

Internal Title: Expert Science & Technology

Location: Durham, NC

The Expert, Science & Technology - Upstream/Cell Culture, is responsible for cell & gene therapy (AAV and LVV) upstream process development, optimization and scaling up/down, process characterization, technology transfer and GMP manufacturing support.

About the Role

Key Responsibilities

- Leads and support activity with cross-functional organizations to plan, execute, and document experiments and early manufacturing that define the process, and method of delivery to the

clinical and commercial sites.

- Design and execution of time-sensitive experiments, studies, and capturing related data and knowledge, to advance the development products from Research to Development to GMP manufacturing.
- Maintains constant awareness of novel biochemical and biophysical technologies for gene therapy production and characterization. Keeps up to date with the scientific literature and developments in the field. Applies understanding of regulatory expectations to process development strategies. Contributes to process risk assessments. Justifies development strategies and experiment designs.
- Designs and applies DOE and QbD studies to develop, refine, optimize and characterize cell culture and vector production processes. Executes experiments and troubleshoot process and equipment. Conducts laboratory studies to enhance gene therapy manufacturing technologies, capabilities and processes (such as media development, bioreactor fed-batch and perfusion process development, optimization and scale-up).
- Supports initiatives for new technology development and continuous improvement projects.
- Provides support for process, analytical, and characterization knowledge related to the production of gene therapy products, and the raw materials needed to make them.
- Tracks records of collaborative relations with groups such as research and development, analytical development, and pilot scale operations.
- Ensures all documentation and reports are accurate, complete, and suitable for using in support of production, characterization, and regulatory filings.
- Writes detailed experimental protocols, develop Bill of Materials (BOM), executes and documents experimental studies according to Standard Operating Procedures (SOPs) or established practices, review and report data.
- Creates and revise SOPs for equipment and process operations.
- Lead the authoring of technical reports and CMC sections for regulatory filings.

Essential Requirements:

- Bachelor's degree in biochemistry, chemical engineering, bioengineering, or related technical field with 4 years relevant experience; or Master's with 2 years relevant experience; or PhD with academic experience (Recent PhD welcome to apply).
- Extensive experience with production of virus or biologics from mammalian expression systems.
- Hands on experience with different cell lines, bioreactors, and scale-down model
- Organized and systematic approach to viral or biologic production.
- Ability to multi-task and meet tight timelines is essential.
- Proficient in statistical analysis principles and approaches. Working knowledge and experience with Design of Experiment (DoE).
- Ability to analyze data to make data-driven decisions and further progress development strategies. Innovative with a continuous improvement mindset. Excellent team player with good
- communication skills.
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Desired Requirements

- Knowledge with a variety of biopharmaceutical purification processes is desired
- Knowledge of viral cell/gene therapy and previous experience with LVV process development is preferred.

The salary for this position is expected to range between \$93,800 and \$174,200 per year.

The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors.

Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards.

US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

To learn more about the culture, rewards and benefits we offer our people click [here](#).

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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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>

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Development

Business Unit

Universal Hierarchy Node

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USA

状态

North Carolina

站点

Durham

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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