Senior Expert, Science & Technology (Analytical Project Lead)

Job ID
REQ-10048637

4月 18, 2025

USA

摘要

The Analytical Development Operations (ADO) group is responsible for developing analytical technologies and applying them to support viral vector development for cell and gene therapies. ADO supports chemistry, manufacturing and control (CMC) activities from the earliest stages of product candidacy through commercial licensure. Within ADO, the Senior Expert, Science & Technology, Analytical Project Lead (APL) APL is responsible for identifying critical quality attributes (CQA) of a viral vector candidate and developing analytical strategies and methods for monitoring CQAs throughout product development. The APL works within a cross functional CMC team to design, coordinate, and execute studies that demonstrate Novartis understands and appropriately controls the quality of our product and process. This APL position offers the opportunity to develop and apply rapidly advancing analytical technologies necessary to ensure Novartis consistently delivers safe and effective cell and gene therapeutics.

About the Role

#LI-Hybrid

Key Responsibilities:

- Produce product CQA assessment, analytical strategy, specifications, and comparability strategies/criteria
- Lead the development, qualification, transfer, and validation of analytical methods among multiple internal and external analytical laboratories
- Facilitate forecasting and allocation of internal analytical resources
- Manage scope, timelines, and budget activities with external analytical laboratories
- Lead cross-functional and cross-site product characterization and investigations
- Provide technical expertise and leadership as you collaborate within and across cross-functional teams to support process development and establish control strategy
- Provide strategic recommendations across the network
- Serve as a key scientific and technical representative on cross-functional teams (CMC, Regulatory, Quality, Manufacturing, etc.)
- Write, review, and/or approve experimental protocols/reports and regulatory submissions
- Respond to questions from regulatory authorities regarding analytical topics and specifications

Essential Requirements:

- BS/BA in relevant field with 8 years ' , MS with 6 years ' , or Ph.D. with 4 years ' experience in biopharmaceutical industry
- A critical thinking mindset, problem-solving skills, and the interpersonal communication, scientific writing, and presentation abilities to provide effective leadership
- Strong organizational skills and ability to prioritize simultaneous projects and activities
- Proven ability to effectively lead and participate on teams, often via tele/video conference
- Passion for continuous learning and capability to work in a highly dynamic, fast-paced, collaborative environment is key to the success of this role.

- Experience with analytical support for biologic product commercialization, especially in cell/gene therapy field
- Strong background in protein/nucleic acid chemistry/biochemistry/analytical chemistry
- Experience preparing regulatory filings and other correspondence/interactions with regulatory agencies

Desirable Experience:

- Project management experience
- Familiarity with GMP practices and requirements (e.g. change control) and regulations (FDA/EMA/ICH etc.)

The pay range for this position at commencement of employment is expected to be between $114,100 and $211,900/year; however, while salary ranges are effective from 1/1/25 through 12/31/2025, 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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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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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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Development

Business Unit
Innovative Medicines

地点
USA

状态
North Carolina

站点
Durham

Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Alternative Location 1
East Hanover, New Jersey, USA

Functional Area
Research & Development

Job Type
Full time

Employment Type

Regular

Shift Work
No

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