Sr. Manager, Stability, Material, and Quality System Management, Cell and Gene Therapy Analytical Operations

Job ID
REQ-10031733

2月 28, 2025

USA

摘要

Location: East Hanover, NJ, United States (On-site)
Position will be onsite.
LI#onsite
Join Our Vision: At Novartis, we are on a transformative journey in cell and gene therapy, pushing the boundaries of medical innovation. We are currently seeking a dynamic and visionary Sr. Manager to lead our Cell and Gene Therapy Analytical Operations Stability, Material, and Quality System Management group. This pivotal role is not just about leading a team; it ' s about shaping the future of cell and gene therapy.

Your Role: As the Senior Manager, Stability, Material and Quality System Management you ' ll be leading a team responsible for raw materials, sample management, stability studies and quality system management in the Cell and Gene Therapy Analytical Operations organization. You will ensure the testing, release, and stability of raw materials and finished products meet quality standards and regulatory requirements for Novartis Cell and Gene clinical products. Reporting to the Head of Cell and Gene Therapy Analytical Operations, you will be a vital link between Analytical

Development, Pilot Plant manufacturing, Quality Assurance and Technical Operations.

About the Role

Key Responsibilities:

- Lead and manage a team of Quality Control associates in performing routine raw material inspection and supporting raw material specifications, including justification of specifications for Novartis Cell and Gene products in the clinical stages.
- Oversee various stability studies (long terms, accelerated, stressed) on Drug Substance, Drug Product or Final Product for Cell and Gene therapies, both internally and externally.
- Coordinate shift work, activities and priorities to meet the required business timelines, serving as the primary point of contact for communication with management.
- Develop strategies for trending stability data and monitoring stability trends for all studies related to viral vectors or finished products in real time.
- Design and lead comprehensive studies related to raw materials and stability, ensuring scientific rigor and regulatory compliance. Influence internal stake holders and justify approaches to drive alignment. Respond efficiently and effectively to Health Authority queries regarding these areas.
- Organize, plan, and support team members with technical questions, ensuring group ' s efficiency and accountability. Mentor and coach team members, facilitating their career growth and professional development.
- Ensure that all activities, follow current Good Manufacturing Practices, and Health, Safety, and Environmental policies per the global/local Novartis standards.
- Lead and perform Out-of-Specification (OOS)/Our-of-Expectation (OOE) investigations. Manage change controls, deviations, and CAPA implementation.
- Support laboratory inspections and audits, including follow-up actions to address any findings.
- Foster clear and precise communication within the team and across departments to ensure transparency, collaboration, and efficiency.
- Plan and manage resources and budget including Capital Expenditure (CapEx).

Requirements:

- BS with a minimum of 6 years of industry experience in Stability and/or Material management in biotech or pharmaceutical companies, including at least 2 years of direct people management experience in a Quality Control environment.
- Extensive knowledge and experience in material management and stability programs for Cell and Gene or Biological products.
- Extensive experience working in a GMP environment.
- Familiarity with ICH and agency guidelines related to raw materials and stability for Cell and Gene Therapies.
- Strong communication, scientific writing, and presentation skills.

Desirable Requirements:

- Experience in resource and budget management.
- Experience with electronic systems such as SAP, LIMS, and Quality Management Systems.

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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Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $108,500-$201,500/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.

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Development

Business Unit
Innovative Medicines

地点
USA

状态
New Jersey

站点
East Hanover

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

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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