Sr. Manager of Bioanalytics, Cell and Gene Therapy Analytical Operations (Mon-Thurs)

Job ID
REQ-10034288

1月 17, 2025

USA

摘要

Position: Sr. Manager of Bioanalytics, Cell and Gene Therapy Analytical Operations
Location: East Hanover, NJ, United States (On-site)
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 spearhead our Cell and Gene Therapy Analytical Operations Bioanalytics group. This pivotal role is not just about managing a team; it ' s about shaping the future of cell and gene therapy.
Your Role: As the Senior Manager, you ' ll be at the forefront of our mission, guiding a talented group of Quality Control associates dedicated to clinical testing and method validation activities for Novartis ' Cell and Gene clinical products. Reporting to the Associate Director of Bioanalytics, Cell and Gene Analytical Operations, you will serve as a crucial link among Analytical Operations, Analytical Development, Pilot Plant manufacturing, Quality Assurance, Instrument Validation and Technical Operations.

About the Role

Key Responsibilities:

- Shift position-Monday-Thursday. Work on shifts during weekdays and one or both weekend days if required by business needs. Shift will be fixed according to business needs. Act as the primary point of contact for communication to management during shifts.
- Coordinate and supervise all clinical testing and method validation activities of the assigned team to meet timelines. Provide guidance and technical support to team members, ensuring efficiency and accountability within the group.
- Mentor and coach team members to foster career development and advancement.
- Ensure qualification status of critical reagents.
- Lead OOS, OOE and deviation investigations. Manage change controls and CAPA implementation and ensure timely closure of quality records.

- Ensure lab personnel training is up to date, including for temporary staff ad new associates.
- Support lab GMP inspections and ensure timely implementation and closure of actions.
- Support the trending of analytical methods and tracking of invalid rate, communicate any underlining issues to management promptly and identify solutions to resolve them.
- Author, review and approval Quality Control technical documents. Maintain methods and specifications compliant with Novartis policies and procedures, regulatory guidance and industry standards.
- Ensure that all activities, including equipment utilization, adhere to current Good Manufacturing Practices, and Health, Safety, and Environmental policies per global and local Novartis standards.
- Plan and manage resources efficiently.

Requirements:

- Bachelor ' s degree with a minimum of 6 years of quality control experience in biotech or pharmaceutical companies, including at least 2 years of direct people management experience.
- Must have knowledge of cGMP, ICH guidelines, USP/EP/JP, and 21CFR Part 11.
- Working knowledge of qPCR/dPCR, Flow Cytometry, ELISA, cell-based potency and liquid chromatography, and compendial methods.
- Strong communication, writing and presentation skills.

Desirable Requirements:

- Experience with Cell and Gene products is strongly preferred.
- Knowledge with LIMS, SAP system, various quality management systems.
- Knowledge with 5S and lean project methodologies.

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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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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Business Unit
Innovative Medicines

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USA

状态
New Jersey

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

Functional Area
Quality

Job Type
Full time

Employment Type
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Shift Work
No

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REQ-10034288

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