NOVARTIS

Senior Manager, Equipment and LIMS, Cell and Gene Therapy Analytical Operations

Job ID
REQ-10031593
Dec 16, 2024
USA

Summary

Location: East Hanover, NJ, United States
Position is onsite
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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 Equipment and LIMS group. This pivotal role is not just about leading a team; it's about shaping the future of cell and gene therapy.

As the Sr. Manager, Equipment & LIMS you'll be at the forefront of our mission, guiding a talented group of Quality Control associates dedicated to enhancing the digital landscape supporting QC laboratories for Novartis' Cell and Gene clinical products. Reporting to the Head of Cell and Gene Therapy Analytical Operations, you will serve as a vital link among Analytical Development, Pilot Plant manufacturing, Quality Assurance, Instrument Validation and Technical Operations.

About the Role

Key Responsibilities:

- Lead and manage a team of analysts to work closely with the Global GDLIMS team, ensuring the implementation of new systems and improvements of existing systems, including system configuration specification, system administration SOP and executing test scripts following cGxP for Novartis Cell and Gene products in the clinical stages.
- Shape and deliver the long-term strategic vision for the Quality Control Digital roadmap by coordinate activities and priorities to meet the required business timelines. Serve as the primary point of contact for communication with management.
- Oversee equipment qualifications and validation protocols, risk management tools, gap analysis, CAPA and validation exceptions/deviations for Computer and IT systems. Support initial and routine system risk assessment and testing activities.
- Organize, plan, and support team members with QC equipment or LIMS technical questions and problems, to ensure group efficiency and accountability. Mentor and coach team members to facilitate career growth.
- Ensure that all activities, including training and equipment management, follow current Good Manufacturing Practices, and Health, Safety, and Environmental policies per the global and local Novartis

standards.
- Manage change controls, deviations, and CAPA implementation related to QC instrument or GDLIMS.
- Support laboratory inspections and audits, including follow-up actions.
- Plan and manage resources and budget, including capital expenditure (CapEx).

Requirements:

- BS with a minimum of 6 years of industry experience in biotech or pharmaceutical companies, including at least 2 years of direct people management experience in QC digitalization projects.
- Excellent understanding of cGXP requirements and good documentation practices related to systems, equipment and instrumentation within the pharmaceutical industry
- Strong working knowledge of ISPE guidance and 21 CFR Part 11 compliance
- Strong communication, writing and presentation skills.

Desirable Requirements:

- Experience in resource and budget management.

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 $112,000-$169,200/year; *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.

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers who are focused on building and advancing a culture of inclusion that values and celebrates individual differences, uniqueness, backgrounds and perspectives. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to fostering a diverse and inclusive workplace that reflects the world around us and connects us to the patients, customers and communities we serve.

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
State
New Jersey
Site
East Hanover
Company / Legal Entity
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Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work

No
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Job ID
REQ-10031593

Senior Manager, Equipment and LIMS, Cell and Gene Therapy Analytical Operations

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