Associate Director of Microbiology, Cell & Gene Therapy Analytical Operations

Job ID
REQ-10031575
Dic 16, 2024
USA

Sommario

Location: East Hanover, NJ, United States (On-site)
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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 Associate Director to spearhead our Cell and Gene Therapy Analytical Operations Microbiology group. This pivotal role is not just about leading a team; it's about shaping the future of cell and gene therapy.
As the Associate Director of the Microbiology group, you'll be at the forefront of our mission, guiding a talented group of Quality Control Microbiology analysts dedicated to routine testing and microbiology method qualification for Novartis Cell and Gene products in the clinical phase. Additionally, you will oversee environmental monitoring activities for the Pilot Plant manufacturing facilities. Reporting to the Head of Cell and Gene Therapy Analytical Operations, you will be a vital link among Analytical Development, Pilot Plant manufacturing, Quality Assurance and Technical Operations.

About the Role

Key Responsibilities:

- Lead and manage a team of Quality Control Microbiology analysts to perform routine product release and stability testing for sterility and endotoxin for Novartis Cell and Gene products in the clinical phase.
- Oversee shift work, manage the environmental monitoring program, and coordinate the activities and priorities of the assigned team to meet the required business timelines. Serve as the primary point of contact for communication to management during shifts.
- Lead microbiology method qualification, validation and transfer activities, including study design, reviewing, and approving study protocols and reports.
- Develop strategies for microbiology method trending and routinely monitor assay performance to ensure data integrity and consistency.
- Organize, plan, and support team members with technical questions and problem-solving to ensure group efficiency and accountability. Mentor and coach team members, facilitating career growth and professional development.
- Ensure compliance with current Good Manufacturing Practices (cGMP), as well as Health, Safety, and Environmental policies per global and local Novartis standards.
- Lead and perform Out-of-Specification (OOS) and Out-of-Expectation (OOE) investigations. Manage change controls, deviations, and Corrective and Preventative Action (CAPA) implementation.
- Support laboratory inspections and audits, including addressing follow-up actions and ensuring

continuous improvement.
- Plan and manage resources and budget, including capital expenditure (CapEx) requirements.
- Manage and support external vendor management activities to ensure the quality and compliance of external services and supplies.
- Collaborate closely with cross-functional teams, including Manufacturing, Quality Assurance, Regulatory CMC, and Analytical Development, to ensure alignment and effective communication of quality control activities.
- Stay abreast of industry trends, regulatory updates, and advancements in microbiological testing technologies, providing technical expertise and leadership to drive continuous improvement and innovation.

Requirements:

- BS with a minimum of 8 years of industry experience in Microbiology in biotech or pharmaceutical companies. Minimum of 4 years of direct people management experience in a Quality Control environment.
- Flexibility to work different shifts, weekends, and overtime, as required by business needs.
- Extensive knowledge and experience of Cell and Gene Therapy Quality Control methods and compendial requirements (Sterility, Endotoxin, Environmental monitoring, APV/APS processes)
- Extensive experience working in a GMP environment.
- 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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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 $144,000-$216,000/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.

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EEO Statement:

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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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