NOVARTIS

Senior Expert, Microbiology, Cell and Gene Therapy Analytical Operations

Job ID
REQ-10031758
Dec 23, 2024
USA

Summary

Location: East Hanover, NJ
Position will be onsite
LI#onsite

About Novartis: At Novartis, we are on a mission to discover new ways to improve and extend people's lives through the power of cutting-edge science and innovation. Our Cell and Gene Therapy division is at the forefront of this revolutionary field, working to transform medicine and deliver transformative therapies for patients in need.
Role Purpose: We are seeking a highly skilled and knowledgeable QC Microbiology Senior Expert to join our Cell and Gene Therapy organization. This pivotal position requires a seasoned professional with deep expertise in microbiology, especially within the context of cell and gene therapy. The QC Microbiology Sr. Expert will lead and manage microbiological testing and ensure compliance with quality and regulatory standards.

About the Role

Key Responsibilities:

Shift position Work on shifts covering daytime / evening and one or both weekend days. Shift will be fixed according to business need.

- Lead microbiological testing activities, including sterility, endotoxin, microbial enumeration, and environmental monitoring for Cell and Gene Therapy products.
- Develop, validate, and implement robust microbiological methods and assays, ensuring compliance with Good Manufacturing Practices (GMP) and regulatory guidelines.
- Perform routine testing, data analysis, and result interpretation to ensure the highest level of product quality and safety. Providing technical assistance to external and internal departments regarding microbiology enquiries.
- Manage the environmental monitoring program and ensure timely identification and mitigation of potential risks.
- Collaborate with cross-functional teams, including global AS&T, Quality Assurance, Manufacturing, Analytical Development, and Regulatory Affairs, to achieve internal alignment and ensure microbiological integrity throughout the product lifecycle.
- Lead investigations for microbiological Out-of-Specification (OOS) results, deviations, and non-conformances, implementing effective corrective and preventive actions (CAPAs).

- Provide technical expertise and guidance to the QC Microbiology team, training and mentoring associates to ensure technical proficiency and professional growth.
- Author revision of SOPs, WPs, Forms, laboratory test records as required using appropriate electronic systems.
- Conduct risk assessments and develop strategies to mitigate microbiological risks associated with Cell and Gene Therapy products.
- Support regulatory inspections and audits, providing expert responses and facilitating compliance with all regulatory requirements.
- Stay current with industry trends, advancements, and regulatory updates related to microbiology and Cell and Gene Therapy, ensuring continuous improvement and innovation within the QC Microbiology function.
- Maintain accurate and detailed documentation of all activities in accordance with regulatory and internal quality standards.
- Working knowledge of LabWare, LIMS and/or other QC data systems.

Requirements:

- BS, MS or PhD in Microbiology, Biotechnology, Life Sciences, or a related field.
- Minimum of 8 years of industry experience, including at least 4 years in Microbiology. Experience in Cell and Gene therapy preferred, experience in Biologics is considered.
- Proven expertise in microbiological testing methods, including sterility, endotoxin, microbial enumeration and identification, and environmental monitoring.
- Extensive experience working in a GMP-regulated environment.
- Strong understanding of regulatory requirements and guidelines related to microbiology, including ICH, USP, EH and FDA.
- Excellent analytical, problem-solving, and decision-making skills.
- Excellent communication, scientific writing, and presentation skills.
- Highly organized and detail-oriented, with the capacity to manage multiple projects and priorities simultaneously.

Preferred Qualifications:

- Experience in Quality Control microbiology for Cell and Gene Therapy products.
- Familiarity with quality management systems (i.e. Agile, Trackwise, Veeva) and laboratory information management systems (LIMS).

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 $98,700-$183,300/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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Innovative Medicines
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State
New Jersey
Site
East Hanover
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Job Type
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Employment Type
Regular
Shift Work
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REQ-10031758

Senior Expert, Microbiology, Cell and Gene Therapy Analytical Operations

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