Associate Director, Rapid Sterility

Job ID
REQ-10042102

6月 06, 2025

USA

摘要

Location: East Hanover, New Jersey, on site
Department: Cell Therapy Analytical Development and Operations
Position Overview:
Bench to bedside! We are seeking a highly motivated and experienced Associate Director to lead the development and implementation of rapid sterility methods for our cell therapy programs. This role is critical for enabling faster batch release and will significantly impact the success of our cell therapy products. The successful candidate will work closely with cross functional teams, including Development, Operations, Quality Assurance, Regulatory, and Manufacturing, to ensure the timely delivery and release of high-quality cell therapy products. This individual will uphold Novartis Values & Beliefs and Code of Ethics to successfully support our bold mission of delivering effective CAR-T cell products for patients in need.

About the Role

Key Responsibilities:

- Lead the design, development, validation, and implementation of rapid sterility testing methods for cell therapy products.
- Develop and optimize procedures for sterility testing to ensure compliance with regulatory standards and guidelines.
- Collaborate with Regulatory CMC team to prepare and review regulatory submissions and responses related to sterility testing methods.
- Serve as subject matter expert in sterility testing, providing guidance and support to project teams and stakeholders.
- Drive continuous improvement initiatives to enhance sterility testing efficiency and reliability.
- Conduct risk assessments and implement mitigation strategies for sterility testing processes.
- Stay current on industry trends, advancements, and regulatory changes related to sterility testing and cell therapy.
- Establish and maintain relationships with external vendors, service providers, and regulatory agencies.
- Prepare and present technical reports, summaries, protocols, and standard operating procedures (SOPs).

Qualifications:

- Bachelors degree, M.S., or Ph.D in Microbiology, Cell Biology, Biotechnology or a related discipline with a proven track record. Advanced education degree is preferred
- At least 8 years of experience in industry, academia or relevant experience
- Strong understanding of regulatory requirements for sterility testing in the cell therapy, gene therapy, biologics or related area (e.g. FDA, EMA, ICH guidelines) is required
- Strong ability with self directed learning to figure things out by reading scientific papers, keeping up with industry trends, and understanding regulatory guidance
- Excellent technical leadership skills, with a team player mentality.
- Demonstrated ability to work independently and as part of a multidisciplinary team.
- Excellent problem-solving skills and the ability to handle multiple projects simultaneously.
- Strong written and verbal communication skills, with the ability to clearly present complex scientific data to various audiences.

Preferred Qualifications:

- Experience in cell and gene therapy product development and manufacturing
- Knowledge of rapid microbial detection systems and advanced microbiology techniques.
- Familiarity with statistical analysis for method validation
- Prior experience working with health authorities or regulatory inspections related to sterility methods
- Industry experience in the development and implementation of rapid microbiology assays for routine batch release
- Proficiency in the development, validation, and implementation of testing methods in a GMP environment is highly desirable

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of

employment is expected to be between $145,600-$270,400; *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.

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

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

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

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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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Development

Business Unit
Universal Hierarchy Node

地点
USA

状态
New Jersey

站点
East Hanover

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

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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Associate Director, Rapid Sterility

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