NOVARTIS

Global Senior Director, Sterility Assurance

Job ID
REQ-10076012
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США

Сводка

Are you ready to shape sterility assurance strategy with a strong U.S. regulatory focus while influencing manufacturing quality across the Novartis network? As Global Senior Director, Sterility Assurance, you will set sterility assurance and aseptic processing standards with primary accountability for aligning U.S. manufacturing operations to FDA expectations. Partnering closely with senior leaders across Quality, Manufacturing, Engineering, and Technical Operations, you will drive inspection readiness, strengthen aseptic capabilities, and guide complex, cross-platform initiatives. This role blends deep technical expertise with enterprise leadership—protecting product quality, safeguarding patient supply in the U.S., and enabling consistent sterility assurance excellence globally.

#LI-Remote
Other Locations: Morris Plains, New Jersey, United States

About the Role

Key Responsibilities

- Lead sterility assurance strategy with primary focus on U.S. manufacturing and FDA regulatory expectations.
- Drive U.S. inspection readiness and remediation programs, partnering with sites to prevent repeat observations.
- Serve as Global Process Owner for Sterile Operations, governing and harmonizing aseptic processes across platforms and sites.
- Provide proactive sterility assurance leadership during the design and qualification of new production facilities and microbiology laboratories, ensuring that layouts, processes, and controls meet all relevant regulatory, aseptic, and quality compliance requirements.
- Serve as subject matter expert in microbiological topics, leading resolution of sterility and contamination escalations.
- Lead complex, cross-functional and cross-site projects delivering U.S. sterility assurance priorities and global quality initiatives.
- Monitor sterility assurance performance indicators and deliver clear, executive-level insights to enable timely, compliant decision-making.
- Represent Novartis externally as a recognized sterility assurance expert, supporting U.S. industry engagement and global alignment.

Essential Requirements

- Bachelor’s degree in pharmacy, chemistry, microbiology, or a related scientific discipline; advanced degree preferred.
- Minimum of 10 years of experience in global, cross-disciplinary project management and leadership roles within the pharmaceutical industry, preferably in strategic Site or global QA Operations and/or Compliance roles. Pharmaceutical production experience is indispensable.
- Extensive experience delivering sterility assurance leadership within U.S. pharmaceutical manufacturing and FDA-regulated environments.
- Deep technical expertise in microbiology, aseptic processing, and sterile manufacturing operations.
- Demonstrated success leading enterprise-level quality initiatives across multiple sites and manufacturing platforms.
- Proven ability to influence senior stakeholders, lead cross-functional teams, and drive complex, high-impact programs.
- Travel up to 25%

The salary for this position is expected to range between $168,000 and $ 312,000 per year. The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors. Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards. US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

To learn more about the culture, rewards and benefits we offer our people clickThrive Together.

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: Learn about all the ways we’ll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers. 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.

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.

Дивизион
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Business Unit
Human Resources
Место
США
Состояние
Remote, US
Сайт
Remote Position (USA)
Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation
Alternative Location 1
Morris Plains, New Jersey, США
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No

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