NOVARTIS

Sterility Assurance Expert

Job ID
REQ-10075576

4月 27, 2026

USA

摘要

#LI-Onsite

Location: Morris Plains, NJ, United States

Relocation Support: This role is based in Morris Plains, NJ, United States. Novartis is unable to offer relocation support: please only apply if accessible.

This is an opportunity to play a critical role in protecting patients by shaping and defending sterility assurance strategies for advanced aseptic manufacturing. As the Sterility Assurance Expert, you will provide hands - on technical leadership across aseptic processing, microbial control, environmental monitoring, and contamination investigations, ensuring every decision is scientifically sound, data - driven, and inspection - ready. Partnering closely with Operations, Quality, and Technical teams, you will serve as a trusted authority who drives risk - based decisions, strengthens compliance with evolving regulatory expectations, and continuously improves sterility assurance programs in a highly regulated, mission - critical environment.

About the Role

Key Responsibilities

- Serve as site sterility assurance expert for aseptic processing and microbial control programs
- Design, maintain, and improve sterility assurance strategies aligned with global regulatory expectations
- Lead sterility - related deviations, contamination investigations, and risk - based decision making
- Own environmental and personnel monitoring strategies, including trending, escalation, and continuous improvement
- Author, review, and approve sterility assurance documentation, validations, and technical rationales
- Represent sterility assurance during regulatory inspections, audits, and quality governance forums
- Partner cross - functionally to resolve sterility risks and strengthen inspection readiness and compliance

Essential Requirements

- Bachelor ' s degree in a scientific or technical field, preferably Microbiology or a related discipline
- Extensive experience supporting sterility assurance programs in regulated biopharmaceutical manufacturing environments
- Deep understanding of aseptic processing, microbial control strategies, and contamination risk management
- Proven experience leading sterility - related investigations, environmental monitoring programs, and corrective action planning
- Strong knowledge of global regulatory expectations, including United States and European health authority requirements
- Ability to apply scientific judgment, analyze complex data, and communicate clear, compliant recommendations

Desirable Requirements

- Experience supporting sterility assurance activities for aseptic cell or gene therapy manufacturing
- Direct participation in regulatory inspections with ownership of sterility assurance topics and responses

The pay range for this position at commencement of employment is expected to be between $108,500 and $201,500 per year; however, while salary ranges are effective for a defined period, fluctuations in the job market may necessitate adjustments. Final pay determinations will depend on a

variety of factors, including but not limited to geographic location, experience level, knowledge, skills, and abilities. The total compensation package may also include other elements, such as a performance - based bonus and a full range of medical, financial, and other benefits, including retirement programs and paid time off. Details of participation in these benefit plans will be provided if an offer of employment is made. Employment with Novartis is at - will, and the company reserves the right to modify compensation at any time based on individual, business, or market factors.

To learn more about the culture, rewards and benefits we offer our people click here.

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.

部门

Operations

Business Unit
Quality

地点
USA

状态
New Jersey

站点
Morris Plains

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

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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(KalturaPlayer.plugins["transcript"]) { config.plugins["playkit-js-transcript"] = { position: "right", // Default: bottom;('left', 'right', 'top', 'bottom') to enable transcript. expandMode: "over", // Default: alongside;('alongside', 'hidden', 'over') expandOnFirstPlay: false, showTime: true, downloadDisabled: false, printDisabled: false, disable: true }; } if (KalturaPlayer.plugins["preventSeek"]) { config.plugins.preventSeek = { preventSeekForward: false, preventSeek: false }; } config.plugins.floating = { disable: true }; if (KalturaPlayer.plugins["navigation"]) { config.plugins.navigation = { position: "right", expandMode: "over", expandOnFirstPlay: false, visible: false }; } if (KalturaPlayer.plugins["hotspots"]) { config.plugins['playkit-js-hotspots'] = { disable: true }; } if (KalturaPlayer.plugins["moderation"]) { config.plugins['playkit-js-moderation'] = { disable: true }; } if (KalturaPlayer.plugins["info"]) { config.plugins['playkit-js-info'] = { disable: true }; } if (KalturaPlayer.plugins["share"]) { config.plugins.share = { disable: true }; } config.ui.uiComponents = []; if (KalturaPlayer.plugins["googleAnalytics"]) { config.plugins.googleTagManager = {}; config.plugins.googleTagManager.customEventsTracking = {}; config.plugins.googleTagManager.containerId = 'GTM-57RJQ5'; config.plugins.googleTagManager.customEventsTracking.custom = []; config.plugins.googleTagManager.customEventsTracking = { preset: { coreEvents: true, UIEvents: false, playlistEvents: false, castEvents: false } }; }

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