NOVARTIS

Senior Director, Sterility Assurance

Job ID
REQ-10084697

七月 31, 2026

China

摘要

This role provides strategic leadership for aseptic processing and sterility assurance, work-ing across the Novartis manufacturing network to drive harmonized standards and ap-proaches. It ensures alignment with FDA and international health authority expectations by overseeing inspection readiness, GMP and Annex 1 implementation, remediation pro-grams, capability development in aseptic techniques, and monitoring of sterility assurance performance indicators. It also drives enterprise-level strategic thinking by leading complex cross-functional and multi-platform initiatives, managing multidisciplinary project portfoli-os, and influencing key stakeholders to deliver collective impact, unified decision-making, and long-term quality excellence.

About the Role

- Provide sterility assurance and aseptic expert advice including coaching and appropriate technical support to ensure site readiness for Health Authority and GGA inspections by supporting sites in their preparation, support and review of documentation preparation (i.e.

storyboards for complex cases, etc.)

- Establish and verifies that all actions related to FDA, EMA and other local health authority inspections (i.e. Beijing Municipal Medical Products Administration (BJMPA), Chinese Food and Drug Administration (cFDA)) are understood and implemented by the sites, avoiding re-occurrence of systematic observations and Warning Letters.
- Assures quality actions are executed and the overall plans are closed per the required timelines and that future quality plans are aligned with enterprise and network priorities.

- Primary Responsible for optimization and update of aseptic processes (as e.g. cleaning and disinfection programs, microbiological monitoring and sterilization techniques) between sites and platforms within the Novartis manufacturing network.

- Global Process Owner for various level 4 process steps within the Sterile Operations quality system and responsible person for Functional Representatives.
- 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.
- SME in microbiological topics, provide ad-hoc support to the sites and within the network.

- Drive resolution of escalations for specific topics (i.e. Microbial contaminations, sterility issues, etc.) with the manufacturing sites if needed, and in collaboration with the other members of the platform (i.e. QA operations, QA compliance lead, QC/AS&T lead)

- Share best practices between the different sites (e.g by authoring Novartis position papers) and lead assigned benchmarking exercises as required.

- Own, Monitor and act as Primary contact for the sterility assurance from the sites and define improvement plans as appropriate.
- Support the execution of the aseptic governance and training programs in collaboration with engineering and MS&T to support sites in development, training and understanding of aseptic topics
- Review site ' s Aseptic KPI trending, manage adequate timely action plans are planned if required and provide high-quality reports to high leadership.
- Represent Novartis externally as a recognized expert in sterility assurance, ensuring strong participation in key industry platforms (e.g., Biophorum) and leading the definition of strategic priorities for external engagement and cross - industry alignment.
- Drive consistent quality and technical issue resolution in the network in line with international cGMP standards
- Lead cross-platform, network projects and harmonization initiatives as assigned
- Drive cross platform communication (e.g by leading regular official discussion forums) for knowledge exchange, support of discussion and decision making for aseptic processing topics
- Create system to capture lessons learned (e.g. topics discussed, near misses) during internal and external audits, define appropriate actions, and share them among the network.
- Provides input for the selection, people development and performance evaluation, development planning and participating in recruiting process of the Aseptic experts within the manufacturing sites.
- Shape the long-term sterility assurance vision, ensuring strategic alignment between enterprise priorities, evolving regulatory expectations, and operational needs across the

Novartis network.

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)

部门
Operations

Business Unit
Quality

地点
China

站点
Beijing (Beijing)

Company / Legal Entity
CN06 (FCRS = CN006) Beijing Novartis Pharma Co., Ltd

Functional Area
Quality

Job Type
Full time

Employment Type

Regular

Shift Work
No

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