NOVARTIS

Global Head Sterility Assurance

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REQ-10080057
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Австрия

Сводка

The Global Head Sterility Assurance provides strategic leadership for sterility assurance and aseptic quality across the Novartis manufacturing network. This role leads Quality Assurance leaders and Senior Global Aseptic Processing Experts to ensure aseptic operations comply with cGMP requirements, health authority regulations, and Novartis Quality Manual and Policy standards.

The role oversees sterility assurance performance across approximately 20–30 aseptic manufacturing sites, including Large Molecules, Aseptics, Advanced Therapies, and Radioligand Therapy platforms. It drives alignment, communication, inspection readiness, and sustainable compliance across the network.

Key responsibilities include ensuring readiness for FDA and other health authority inspections, supporting compliance with evolving GMP expectations such as EU GMP Annex 1, tracking remediation actions, and preventing repeat observations. In partnership with Technical Operations and site Quality teams, the role also supports quality programs, aseptic project metrics, documentation standards, and continuous improvement initiatives.

This position is central to harmonizing sterility assurance practices, strengthening quality culture, and advancing patient safety and operational excellence across the global aseptic network.

About the Role

This role requires global travel of up to 30–35%.

Deadline for applications: **19th of June 2026.**

Major Accountabilities:

- Lead the global aseptic processing function across sites and manufacturing platforms with aseptic operations.
- Drive, support, and oversee global aseptic initiatives, including process optimization across the Novartis manufacturing network.
- Ensure site readiness for Health Authority and GGA inspections through effective preparation, support, and follow-up.
- Monitor timely execution and closure of quality actions and remediation plans in line with required timelines.
- Oversee aseptic operations in new production facilities and microbiology laboratories.
- Provide microbiology subject matter expertise and support escalation management for contamination, sterility, and related quality issues.
- Promote best-practice sharing, cross-platform communication, and consistent resolution of technical and quality issues in line with global cGMP standards, including Annex 1.
- Manage aseptic KPI trending, sterility assurance governance, expert networks, training programs, and development of aseptic experts across sites and global functions.

Obligatory requirements:

- Graduate degree in Chemistry, Pharmacy, Microbiology, or a related scientific discipline; Ph.D. or advanced degree preferred.
- 10–15 years of pharmaceutical industry experience, including senior management or leadership roles in Quality Assurance, Quality Operations, Compliance, or global/site quality functions.
- Strong experience in pharmaceutical manufacturing, preferably within an FDA-regulated and global cGMP environment.
- In-depth knowledge of cGMP requirements across the US and EU, including self-inspections, third-party audits, deviation and complaint management, GMP training, and SOP systems.
- Deep technical understanding of microbiology, sterility assurance, and aseptic processing.
- Proven people leadership, stakeholder management, negotiation, communication, and escalation skills across diverse global teams and functions.
- Strong project management experience, with the ability to lead complex cross-functional and global initiatives.
- Fluent English communication skills, both written and spoken.

Why Novartis? Our purpose is to reimagine medicine to improve and extend people’s lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

You’ll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards Commitment to Diversity and Inclusion: Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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 and Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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)

Дивизион
Operations
Business Unit
Quality
Место
Австрия
Сайт
Schaftenau
Company / Legal Entity
AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH
Alternative Location 1
Barcelona Gran Vía, Испания
Alternative Location 2
Morris Plains, New Jersey, США
Alternative Location 3
Puurs, Бельгия
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No

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