

# 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.

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Quality  
Место  
Австрия  
Сайт  
Schafftenau  
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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#### **List of links present in page**

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2. <https://www.novartis.com/about/strategy/people-and-culture>
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5. [https://novartis.wd3.myworkdayjobs.com/en-US/Novartis\\_Careers/job/Schafftenau/Global-Head-Sterility-Assurance\\_REQ-10080057-1](https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Schafftenau/Global-Head-Sterility-Assurance_REQ-10080057-1)

