

Senior Director, Global Sterility Assurance

Job ID
REQ-10085508

8月 13, 2026

Canada

Available in: English | [Fran ç ais](#)

摘要

#LI-Remote

Location: Canada/Remote

Novartis will not offer relocation support for this role.

Are you ready to shape sterility assurance strategy with a strong North America regulatory focus while influencing manufacturing quality across the Novartis network? As the Senior Director, Global 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.

About the Role

Key Responsibilities

- Lead sterility assurance strategy with primary focus on U.S. manufacturing and FDA regulatory expectations.
- Drive North America/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%
- Language : French speaking and writing: Advanced. English speaking and writing: Advanced.

At Novartis Canada, we are determined to be a valued partner and advocate, with a deep understanding of patient needs along the entire care journey - from drug development, to diagnosis, to access and beyond. Part of the way we are doing this is by leveraging data, technology, and partnerships.

Research & Development: we focus on four core therapeutic areas: Cardiovascular, Renal & Metabolic, Immunology, Neuroscience and Oncology. We also develop and deliver treatments through other promoted and established brands, which today are helping millions of patients. Over the last three years, our average annual research and development investment in Canada was over \$30 million, and we conduct clinical trial research in every region throughout Canada.

Commitment to Diversity and Inclusion: Novartis is committed to building outstanding, inclusive work environment and diverse team ' s representatives 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 \(PDF 30 MB\)](#)

部门
Operations

Business Unit
Quality

地点
Canada

站点

Montreal

Company / Legal Entity

CA04 (FCRS = CA004) NOVARTIS PHARMA CANADA INC.

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

```
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false }, components: { fullscreen: { disableDoubleClick: false } }, uiComponents: [ { presets:
['Playback', 'Live'], area: 'BottomBarRightControls', replaceComponent: 'Fullscreen', get:
kPlayer.ui.components.Remove } ] } }; // Check and add plugins only if they exist if
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false, printDisabled: false, disable: true }; } if (kPlayer.plugins["preventSeek"]) {
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false, playlistEvents: false, castEvents: false } };
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```
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window.kalturaPlayerVideos = window.kalturaPlayerVideos || [];  
try {  
  var thumbEmbedPromise =  
    _thumbnailEmbed({config, mediaInfo: {entryId: "1dgfvmafo"}});  
  // _thumbnailEmbed() returns a Promise that resolves with the player instance // when the user clicks the thumbnail. Use .then() to  
  // capture the player directly. thumbEmbedPromise .then(function(player) {  
    window.kalturaPlayerVideos.push(player);  
    // Notify kaltura_dataLayer.js that a new player is ready so it can // attach custom event listeners immediately, regardless of when // the user clicked the  
    // thumbnail relative to page load. document.dispatchEvent(new CustomEvent('kalturaPlayerReady', {  
    detail: { player: player } }));  
  }) .catch(function(error) { console.error(error); });  
} catch (e) { console.error(e.message) }
```

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