

## Vodja zagotavljanja sterilnosti (m/ ž /d) / Sterility Assurance Lead (m/f/d)

Job ID  
REQ-10068349

1月 16, 2026

Slovenia

### 摘要

#LI-Hybrid

Interni naziv pozicije / Internal Job Title: Višji ekspert upravljanja kakovosti - operacije / Senior QA Operations Expert

Ste pripravljeni ustvariti resničen vpliv tam, kjer je to najpomembnejše? Kot Vodja zagotavljanja sterilnosti boste ključni nosilec strategije na področju obvladovanja kontaminacije in aseptične odličnosti v vrhunskem, tehnološko naprednem proizvodnem okolju. S svojo strokovnostjo boste zagotavljali, da vsak sterilni izdelek dosega najvišje globalne standarde - da je varen, skladen s predpisi in dostavljen pravočasno. Pridružite se nam pri vodenju nenehnih izboljšav, mentoriranju ekip ter soustvarjanju procesov, ki vsak dan ščitijo zdravje in življenje bolnikov po vsem svetu.

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Ready to make an impact where it matters most? As Sterility Assurance Lead, you'll be the driving

force behind contamination control and aseptic excellence in a cutting-edge manufacturing environment. Your expertise ensures every sterile product meets the highest global standards, safe, compliant, and delivered on time. Join us to lead improvements, mentor teams, and shape processes that protect patients worldwide.

Relocation Support: This role is based in Ljubljana, Slovenia. Novartis is unable to offer relocation support: please only apply if accessible.

## About the Role

Vaš ključna odgovornosti:

- Vodenje aseptičnega QA nadzora in supervizije aseptičnih procesov (Aseptic Process Simulation - APS).
- Zagotavljanje QA nadzora pri odstopanjih proizvoda/procesa, lokalnih in globalnih eskalacijah, spremembnih kontrolah in presojah ter zagotavljanje ustrezne eskalacije in sanacije kritičnih zadev, povezanih z aseptičnimi procesi.
- Vodenje in/ali sodelovanje v globalnih aseptičnih projektih, vključno z upravljanjem delovnih nivojev na globalni ravni.
- Zagotavljanje nadzora in podpore na področju mikrobioloških vidikov proizvodnje, kot so monitoring okolja, monitoring plinov/vode in monitoring biološke obremenitve (Bioburden).
- Odobritev strategije obvladovanja kontaminacije za lokacijo ter zagotavljanje skladnosti z Aneksom 1 ter podpora pri njenem razvoju in implementaciji.
- Odgovornost za odobritev konceptualnih postopkov na področju aseptičnega vedenja in aseptičnih procesov ter zagotavljanje njihove implementacije in skladnosti z veljavnimi regulativnimi zahtevami.
- Zagotavljanje tehnične strokovnosti za tržne in klinične izdelke v regulatornih razpravah, pri pripravah na inšpekcijske nadzore ter pri regulatornih vlogah.
- Zagotavljanje QA nadzora ter podpora pri razvoju in izvajanju programov usposabljanja na področju mikrobioloških in aseptičnih najboljših praks z namenom krepitev kulture skladnosti in odličnosti.

Vaš doprinos k delovnem mestu:

- Univerzitetna izobrazba iz farmacije, biologije, mikrobiologije ali druge ustrezne naravoslovne oziroma tehnične smeri.
- Vsaj 5 let izkušenj v proizvodnji, razvoju ali drugih strokovnih funkcijah na področju kakovosti.
- Strokovnost na področju zagotavljanja sterilnosti in aseptičnih procesov v farmacevtski proizvodnji.
- Izkušnje z vodenjem preiskav odstopanj, validacij procesov in obvladovanjem sprememb v reguliranem okolju.
- Odlične sposobnosti sodelovanja in komunikacije ter sposobnost vplivanja na medfunkcijske time in delovne žirije.
- Tekoče znanje angleškega jezika.

Z izbranim kandidatom bomo sklenili delovno razmerje za nedoločen čas poskusno dobo 6 mesecev. Prijavo oddajte z življenjepisom v slovenskem in angleškem jeziku.

Ugodnosti in nagrajevanje:

Konkurenčni plačni paket, letni bonus, fleksibilen način dela z možnostjo prilagajanja urnika in deloma od doma, pokojninska shema, možnost vključitve v kolektivno zdravstveno zavarovanje, shema nagrajevanja in priznanja dosežkov, razširjeni program promocije zdravja na področju fizičnega in duševnega dobrega počutja ter delovne obremenitve (Polni življenja), številne priložnosti za učenje in razvoj.

Preberite na špripri nikda spoznate na in e s katerimi bomo spodbujali vašo osebni in profesionalni razvoj:

<https://www.novartis.com/careers/benefits-rewards>

Predani smo raznolikosti in vklju enosti Novartis si prizadeva ustvariti izjemno, vklju ujo delovno okolje in oblikovanje raznolikih timov, saj ti predstavljajo naše bolnike in skupnosti, ki jih oskrbujemo.

Zakaj Novartis: Pomagati bolnikom in njihovim družinam zahteva več kot le inovativno znanost. Potrebna je skupnost zavzetih ljudi, kot ste vi.

V Novartisu cenimo sodelovanje, podporo in navdihovanje drug drugega za razvoj prebojnih terapij, ki spreminjajo življenja pacientov.

Ste pripravljeni ustvariti svetlejšo prihodnost skupaj z nami?

<https://www.novartis.com/about/strategy/people-and-culture>

Pridružitese Novartisu: Ni pravo delovno mesto za vas? Prijavite se v našo bazo talentov, da ostanete v kontaktu z nami in se seznanite z ustreznimi kariernimi priložnostmi, ko se pojavijo: <https://talentnetwork.novartis.com/network>

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Key Responsibilities

- Provide QA oversight and support microbiological/aseptic best practices training program development and execution to foster culture of compliance and excellence.
- Lead aseptic QA oversight and supervision of aseptic processing (Aseptic Process Simulation).
- Provide QA oversight for product/process deviations, local and global escalation, change controls and audits, ensuring escalation and remediation of critical issues related to aseptic processes.
- Lead and/or contribute to global aseptic projects including stakeholder management on a global level.
- Provide oversight and support of microbiological aspects related to manufacturing, such as environmental monitoring, gas/water monitoring, and Bioburden monitoring.
- Approve the Contamination Control Strategy for the site making sure it is compliant with the Annex 1 and support its development and implementation.
- Responsible for approving conceptual procedures in aseptic behavior and aseptic processes and ensuring their implementation as well as ensuring compliance with current regulatory requirements.
- Provide technical expertise for marketed and clinical products in regulatory discussions, inspection preparations and submissions.

## Essential Requirements

- University degree in Pharmacy, Biology, Microbiology, or other equivalent natural or engineering science.
- Minimum 5 years of experience in production, development, or other quality functions in an expert position.
- Demonstrated expertise in sterility assurance and aseptic processing in pharmaceutical manufacturing.
- Experience leading deviation investigations, process validation, and change control in regulated environments.
- Strong collaboration and communication skills; ability to influence cross functional teams and stakeholders.
- Fluency in English.

We offer permanent employment with 6 months of probation period. Submit your application with the CV in Slovenian and English language.

## Benefits and Rewards:

Competitive salary, Annual bonus, Flexible working schedule, tailored to your needs, possibility to work from home, Pension scheme, possibility of joining collective health insurance scheme, Employee Recognition Scheme, Expanded program for the promotion of health in the field of physical and mental well-being and managing workload (Well-being), Unlimited learning and development opportunities.

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 \(PDF 30 MB\)](#)

部门

Operations

Business Unit

Quality

地点

Slovenia

站点

Ljubljana

Company / Legal Entity

SI19 (FCRS = SI019) Novartis farmacevtska proizvodnja d.o.o.

Functional Area

Quality

Job Type  
Full time

Employment Type  
Regular

Shift Work  
No

```
function adjustKalturaPlayer() { var deviceWidth = window.innerWidth ||
document.documentElement.clientWidth || document.body.clientWidth; var mediaElement =
document.getElementById("kalturaplayer69b6a62160916096792023"); var mediaContainer =
mediaElement.closest('.nc-kaltura-media'); var originalWidth = "1200px"; var originalHeight = "674px";
var originalWidthValue = parseFloat(originalWidth); var originalHeightValue =
parseFloat(originalHeight); var mediaType = "video"; var isResponsive = false; // Get computed styles
of the container element. var parentStyles = window.getComputedStyle(mediaContainer); var
finalWidth = parseFloat(parentStyles.width); if (finalWidth <= 0) var config = { targetId:
"kalturaplayer69b6a62160916096792023", provider: { widgetId: "10m7rm1pm", partnerId:
"2076321", uiConfId: "55802022" }, playback: { autoplay: false, autopause: false,
allowMutedAutoPlay: false, loop: false }, sources: { options: {}, startTime: 0 }, plugins: { download: {
disable: true }, "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 } }, ui: { showCCButton: false, settings: { showQualityMenu: true, showSpeedMenu: false },
components: { fullscreen: { disableDoubleClick: false } }, uiComponents: [ { presets: ['Playback',
'Live'], area: 'BottomBarRightControls', replaceComponent: 'Fullscreen', get:
KalturaPlayer.ui.components.Remove } ] } }; config.plugins.preventSeek = { preventSeekForward:
false, preventSeek: false }; config.plugins.floating = { disable: true }; config.plugins.navigation = {
position: "right", expandMode: "over", expandOnFirstPlay: false, visible: false }; config.plugins['playkit-
js-hotspots'] = { disable: true }; config.plugins['playkit-js-moderation'] = { disable: true };
config.plugins['playkit-js-info'] = { disable: true }; config.plugins.share = { disable: true };
config.ui.uiComponents = []; 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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try { var kalturaPlayer = KalturaPlayer.setup(config); // Add the player to the global array. if (typeof
kalturaPlayerVideos !== 'undefined') { kalturaPlayerVideos.push(kalturaPlayer); } else { var
kalturaPlayerVideos = []; kalturaPlayerVideos.push(kalturaPlayer); } // Load the Player for other
media. kalturaPlayer.loadMedia({entryId: "1dgfvmafo"}); setTimeout(() => {
setupAutoPause(kalturaPlayerVideos); }, 500); function setupAutoPause(players) {
```

```
players.forEach((currentPlayer) => { currentPlayer.addEventListener('play', () => {
players.forEach((otherPlayer) => { if (otherPlayer !== currentPlayer && typeof otherPlayer.pause ===
'function') { otherPlayer.pause(); } }); }); }); } catch (e) { console.error(e.message) }
```



**VIDEO**

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

## Accessibility and accommodation

Novartis is 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 recruitment process, or in order to perform the essential functions of a position, please send an e-mail to [diversity.inclusionslo@novartis.com](mailto:diversity.inclusionslo@novartis.com) and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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1. <https://www.novartis.com/careers/benefits-rewards>
2. <https://www.novartis.com/about/strategy/people-and-culture>
3. <https://talentnetwork.novartis.com/network>
4. <https://www.novartis.com/about/strategy/people-and-culture>
5. <https://www.novartis.com/sites/novartis.com/files/novartis-life-handbook.pdf>
6. <mailto:diversity.inclusionslo@novartis.com>
7. <https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Ljubljana/Vodja-zagotavljanja-sterilnosti--m--d----Sterility-Assurance-Lead--m-f-d-REQ-10068349-1>
8. <https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Ljubljana/Vodja-zagotavljanja-sterilnosti--m--d----Sterility-Assurance-Lead--m-f-d-REQ-10068349-1>