

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

Job ID
REQ-10068349

3月 20, 2026

Slovenia

摘要

#LI-Hybrid

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

Ste pripravljeni voditi sterilnost tam, kjer vsak detalj šteje?

V novi aseptični proizvodnji boste kot Vodja zagotavljanja sterilnosti ključni oblikovalec strategije obvladovanja kontaminacije in aseptične odličnosti. S svojo strokovnostjo boste zagotavljali, da vsak sterilni izdelek izpolnjuje najvišje globalne standarde - varen, skladen in pravočasno dostavljen bolnikom.

V tej vlogi boste usmerjali nenehne izboljšave, razvijali kulturo odličnosti in mentorirali ekipe, ki vsak dan ustvarjajo resničen vpliv na zdravje in življenje bolnikov po svetu.

Are you ready to lead sterility assurance where every detail truly matters?

In our new aseptic manufacturing facility, you will play a key role as Sterility Assurance Lead, shaping the site's contamination control strategy and driving aseptic excellence. With your expertise, you will ensure that every sterile product meets the highest global standards—safe, compliant, and delivered to patients on time.

In this role, you will guide continuous improvement, build a culture of excellence, and mentor teams who make a real impact on the health and lives of patients around the world every single day.

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 e ključne odgovornosti:

- Prevzemanje vodilne vloge pri vzpostavljanju in izvajanju usposabljanj aseptičnih in mikrobioloških najboljših praks ter gradnji močne kulture skladnosti in odličnosti na področju aseptike.
- Zagotavljanje QA nadzora nad aseptičnim delovanjem vključno s procesom simulacije aseptičnega polnjenja (Aseptic Process Simulation - APS - Media Fill) ter nadzorom nad ključnimi aseptičnimi aktivnostmi.
- Pregled nad odstopi iz aseptične proizvodnje, spremembami, eskalacijami in presojamiz zagotavljanjem pravočasne raziskave, eskalacije in sanacije kritičnih aseptičnih zadev.
- Vodenje ali aktivno sodelovanje v globalnih aseptičnih pobudah v tesnem sodelovanju s efektivnimi in mednarodnimi ekipami za usklajevanje najboljših praks in dvig globalnih standardov.
- Strokovni nadzor mikrobioloških vidikov proizvodnje vključno z monitoringom okolja, nadzorom plinov in vode ter upravljanjem biološke obremenitve (Bioburden), z jasnim poudarkom na preprečevanju kontaminacije.
- Odgovornost za odobritev in razvoj lokalne strategije obvladovanja kontaminacije (CCS) ter zagotavljanje popolne skladnosti z zahtevami Aneksa 1 in njene učinkovite implementacije.
- Odobritev konceptualnih postopkov aseptičnega vedenja in aseptičnih procesov zagotavljanje njihove pravilne uvedbe in skladnosti z veljavnimi regulativnimi zahtevami.
- Zagotavljanje tehnične strokovnosti za tržne in klinične izdelke, ki podpora regulatornim razpravam, pripravi na inšpekcijske nadzore ter regulatornim vložitvam.

Vaš doprinos k delovnem mestu:

- Univerzitetna izobrazba iz mikrobiologije, biologije, farmacije ali druge ustrezne naravoslovne oziroma tehnične smeri.
- Vsaj 5 let izkušenj v proizvodnji, kakovosti, 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 timove in deležnike.
- Tekoče znanje angleškega jezika.

Z izbranim kandidatom bomo sklenili delovno razmerje za nedoločeno 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 delom od doma, pokojninska shema, možnost vključitve v kolektivno zdravstveno zavarovanje, shema nagrajevanja in priznanja dosežkov, razširjeni program promocije zdravja na področju fizičnega in duševnega obdobja po utjater delovne obremenitve (Polni življenja), številne priložnosti za učenje in razvoj.

Preberite na široki splošni spoznate na in s katerimi bomo spodbujali vaš osebni in profesionalni razvoj:

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

Predani smo raznolikosti in vključenosti. Novartis si prizadeva ustvariti izjemno, vključujoče delovno okolje in oblikovanje raznolikih timov, saj ti predstavljajo naša bolnika 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>

Key Responsibilities

- Drive quality leadership by supporting the development and delivery of microbiological and aseptic best practice training programs, strengthening a culture of compliance and operational excellence.
- Lead QA oversight of aseptic operations, including end to end management of Aseptic Process Simulations (APS) and oversight of critical aseptic activities.
- Oversee product and process deviations, change controls, escalations, and audits, ensuring timely investigation, escalation, and remediation of critical aseptic related issues.
- Lead or actively contribute to global aseptic initiatives, collaborating with cross functional and international stakeholders to harmonize best practices and elevate global standards.
- Provide expert oversight of microbiological aspects of manufacturing, including environmental monitoring, gas and water systems, and Bioburden control, ensuring robust contamination prevention measures.
- Own and approve the site 's Contamination Control Strategy (CCS) ensuring full alignment with Annex 1 requirements and supporting its continuous development and implementation.
- Approve conceptual procedures for aseptic behaviour and aseptic processes, ensuring they are effectively implemented and meet current regulatory expectations.
- Provide technical expertise for marketed and clinical products, supporting regulatory submissions, inspection readiness, and engagement with health authorities.

Key Qualifications

- A university degree in microbiology, biology, pharmacy, or another relevant natural science or technical discipline.
- At least 5 years of experience in manufacturing, quality, development, or other scientific functions within a regulated quality environment.
- Expertise in sterility assurance and aseptic processes in pharmaceutical manufacturing.
- Experience in leading deviation investigations, process validation, and change management in a regulated environment.
- Strong collaboration and communication skills, with the ability to influence cross-functional teams and stakeholders.
- Fluent proficiency 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("kalturaplayer69bf14f9478c9783898663"); 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 < originalWidthValue) {
var config = { targetId:
"kalturaplayer69bf14f9478c9783898663", 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 } } };
```

```
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: "1dgvmafo"}); 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 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>