

Site Quality Head (m/f/d) / Vodja kakovosti (m/ ž /d)

Job ID
REQ-10067249

4月 01, 2026

Slovenia

摘要

#LI-Hybrid
Lokacija / Location: Ljubljana, Slovenia

We are looking for a Site Quality Head to lead and strengthen our site quality organization, ensuring the highest standards of compliance, product quality, and continuous improvement. This is a key leadership role for someone who can build high-performing teams, foster a strong quality culture, and partner across the business to support operational excellence. In this role, you will oversee the site's quality strategy, quality systems, and release standards, ensuring products are manufactured and released in line with applicable regulatory requirements, internal policies, and industry expectations. You will work closely with the Global Quality Platform team and report to the Global Quality Platform Head, serving as a trusted leader for site quality performance and compliance.

You will also play a central role in developing talent, creating an inclusive and accountable team environment, and driving a culture where quality is embedded in everything we do. By combining strong people leadership with deep quality expertise, you will help ensure inspection readiness, strengthen stakeholder confidence, and support the long-term success of the site and wider organization.

Iščemo Vodjo kakovosti lokacije (Site Quality Head), ki bo vodil in krepil organizacijo kakovosti na lokaciji ter zagotavljal najvišje standarde skladnosti, kakovosti proizvodov in nenehnih izboljšav. To je ključna vodstvena vloga za osebo, ki zna graditi visoko učinkovite ekipe, spodbujati močno kulturo kakovosti ter sodelovati z različnimi deli organizacije pri podpori operativne odličnosti. Na tej vlogi boste odgovorni za strategijo kakovosti na lokaciji, sisteme kakovosti in standarde sproščanja izdelkov, pri čemer boste zagotavljali, da so izdelki proizvedeni in sproščeni v skladu z veljavnimi regulativnimi zahtevami, internimi politikami in priporočili industrije. Tesno boste sodelovali z Global Quality Platform ekipo ter poročali vodji Global Quality Platform, pri čemer boste delovali kot zaupanja vreden vodja na področju uspešnosti kakovosti in skladnosti na lokaciji.

Imeli boste tudi osrednjo vlogo pri razvoju talentov, ustvarjanju vključujočega in odgovornega timskega okolja ter pri spodbujanju kulture, v kateri je kakovost vključena v vse, kar počnemo. S povezovanjem močnega vodenja ljudi in poglobljenega strokovnega znanja s področja kakovosti boste prispevali k pripravljenosti na inšpekcijske preglede, krepili zaupanje deležnikov ter podpirali dolgoročni uspeh lokacije in širše organizacije.

About the Role

This role can be performed in English, and we welcome applications from international candidates. Relocation support may be available for the selected candidate.

Key Responsibilities:

- Lead the Site Quality organization and ensure robust oversight of all GxP functions.
- Act as Technical Responsible Person (Qualified Person) when required by regulatory standards.
- Develop and implement site quality risk assessments and compliance strategies.
- Ensure adherence to cGxP, data integrity, and eCompliance requirements across operations.
- Drive talent agenda through recruitment, training, coaching, and performance management.
- Foster diversity and deploy career paths and succession plans for site and unit.
- Guarantee associates are GMP-qualified before performing independent tasks.
- Maintain inspection readiness and lead quality aspects of crisis management.
- Assume delegated decision-making responsibilities under on-call management framework.

Essential Requirements:

- Degree-qualified in Pharmacy, Chemistry, Microbiology, or another relevant life sciences discipline.
- 8+ years of Extensive experience in pharmaceutical manufacturing, with a strong background in quality leadership across sterile production, quality assurance, quality systems, or related functions.
- Deep expertise in Aseptic and Sterile manufacturing is essential, including strong knowledge

of aseptic processing, contamination control strategy, cleanroom operations, and the regulatory expectations associated with sterile products.

- Demonstrated ability to lead site quality activities in a highly regulated GMP environment, ensuring compliance, product quality, and continuous improvement.
- Proven success in building, leading, and developing high-performing teams, while fostering a strong quality culture, accountability, and collaboration across the site.
- Ability to operate effectively in complex and ambiguous environments, making sound decisions and setting clear direction in a dynamic business context.
- Solid track record in regulatory inspections and audit readiness, particularly with US FDA inspections; pre-approval inspection experience is highly desirable.
- Strong understanding of applicable regulatory requirements, internal quality standards, and industry best practices, with the ability to translate them into effective site-level quality oversight.
- Fluent in English, with strong written and verbal communication skills.

We offer permanent employment with 6 months of probation period.

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.

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Znanje slovenskega jezika za to vlogo ni zahtevano. Vabimo mednarodne strokovnjake z dobrim znanjem angleškega jezika, za izbranega kandidata pa je lahko na voljo tudi relokacijski paket.

Vaš ključna odgovornosti:

- Vodenje organizacije kakovosti lokacije.
- Implementiranje, zagotavljanje skladnosti in upravljanje praks, predpisanih v Novartisovem proizvodnem procesu.
- Nadzorovanje kakovosti na področju GxP funkcij lokacije.
- Deluje kot tehnična odgovorna oseba lokacije (kvalificirana oseba).
- Zagotavljanje kakovosti izdelkov.
- Zagotavljanje regulatorne skladnosti in implementacija korporativnih standardov in določb

kakovosti.

- Zagotavljanje statusa registracije pri lokalnih zdravstvenih organih (HA).
- Pripravljanje glavne datoteke lokacije za regulativne namene.
- Ocenjevanje tveganja kakovosti za lokacijo.
- Pregledovanje vodenja kakovosti.

Vaš doprinos k delovnem mestu:

- Univerzitetna izobrazba s področja farmacije, kemije, mikrobiologije ali druge ustrezne naravoslovne smeri.
- Najmanj 8 let obsežnih izkušenj v farmacevtski proizvodnji, z močnim ozadjem na področju vodenja kakovosti, vključno s sterilno proizvodnjo, zagotavljanjem kakovosti (QA), sistemi kakovosti ali sorodnimi funkcijami.
- Poglobljeno strokovno znanje s področja aseptične in sterilne proizvodnje, vključno z dobrim poznavanjem aseptičnih procesov, strategij za obvladovanje kontaminacije, delovanja istih prostorov ter regulativnih zahtev, povezanih s sterilnimi proizvodi.
- Dokazana sposobnost vodenja aktivnosti kakovosti na lokaciji v strogo reguliranem GMP okolju, ob zagotavljanju skladnosti, kakovosti izdelkov in nenehnih izboljšav.
- Sposobnost učinkovitega delovanja v kompleksnih in nejasnih okoljih, sprejemanja premišljenih odločitev ter postavljanja jasne usmeritve v dinamičnem poslovnem kontekstu.
- Trdne izkušnje z regulativnimi inšpekcijami in pripravljenostjo na presoje, zlasti z inšpekcijami ameriške agencije FDA; izkušnje s predodobritvenimi inšpekcijami (Pre-Approval Inspections) so zelo zaželene.
- Dobro razumevanje veljavnih regulativnih zahtev, internih standardov kakovosti in najboljših praks v industriji ter sposobnost njihove učinkovite uporabe pri nadzoru kakovosti na ravni lokacije.
- Tekoče znanje angleškega jezika z dobrimi pisnimi in ustnimi komunikacijskimi sposobnostmi.

Z izbranim kandidatom bomo sklenili delovno razmerje za nedoločen časposkusno dobo 6 mesecev.

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 naš priročnik, da spoznate načine, 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 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>

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

```
var config = { targetId: "kalturaplayer69fb1b1ea1f08262277704", provider: { widgetId:
"1Qm7rm1pm", partnerId: "2076321", uiConfId: "55802022" }, playback: { autoplay: false, autopause:
false, allowMutedAutoPlay: false, loop: false }, sources: { options: {}, startTime: 0 }, plugins: {},
sources: { options: {}, startTime: 0 }, ui: { showCCButton: false, settings: { showQualityMenu: true,
showSpeedMenu: false }, css : "/modules/custom/arcticnckalturaaddon/css/kalturavideo.css",
components: { fullscreen: { disableDoubleClick: false } }, uiComponents: [ { presets: ['Playback',
'Live'], area: 'BottomBarRightControls', replaceComponent: 'Fullscreen', get:
KalturaPlayer.ui.components.Remove } ] } }; // Check and add plugins only if they exist if
(KalturaPlayer.plugins["download"]) { config.plugins.download = { disable: true }; } if
(KalturaPlayer.plugins["transcript"]) { config.plugins["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 }; } if (KalturaPlayer.plugins["preventSeek"]) {
config.plugins.preventSeek = { preventSeekForward: false, preventSeek: false }; }
config.plugins.floating = { disable: true }; if (KalturaPlayer.plugins["navigation"]) {
config.plugins.navigation = { position: "right", expandMode: "over", expandOnFirstPlay: false, visible:
false }; } if (KalturaPlayer.plugins["hotspots"]) { config.plugins['playkit-js-hotspots'] = { disable: true }; }
if (KalturaPlayer.plugins["moderation"]) { config.plugins['playkit-js-moderation'] = { disable: true }; } if
(KalturaPlayer.plugins["info"]) { config.plugins['playkit-js-info'] = { disable: true }; } if
(KalturaPlayer.plugins["share"]) { config.plugins.share = { disable: true }; } config.ui.uiComponents =
[]; if (KalturaPlayer.plugins["googleAnalytics"]) { 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: "1dgfvmafo"}); } catch (e) { console.error(e.message) }
```

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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6. <https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Ljubljana/Vodja-kakovosti--m--d---Site-Quality-Head--m-f-d-REQ-10067249-1>
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