

Director, Global TRD QA Sterility Assurance

Job ID
REQ-10083507

7月 24, 2026

Slovenia

摘要

Location: Menges, Slovenia #onsite

Role Purpose:

Establish, lead, and continuously develop the TRD QA Sterile Operations Network, fostering accountability, learning, and collaboration.

Provide specialist knowledge and guidance on sterile and low bioburden processes, ensuring compliance with regulatory requirements.

Implement, harmonize, and continuously improve aseptic standards and best practices across TRD pilot plants and all modalities (Cell and Gene Therapies, Radioligand Therapies, ADC, and New Biological Entities).

Act as a key partner in cross-functional projects, troubleshooting issues and aligning stakeholders on pragmatic solutions and standards.

Mentor and develop members of the TRD QA Sterile Operations Network, addressing critical skills

gaps.

Consult on the evaluation and selection of external contractors for aseptic appropriateness, ensuring integrity of outsourced processes.

Lokacija: Menges, Slovenija #onsite

Namen vloge:

Vzpostaviti, voditi in nenehno razvijati TRD QA Sterile Operations Network ter spodbujati odgovornost, u č enje in sodelovanje.

Nudite strokovno znanje in usmeritve o sterilnih in nizkobiolo š ko zahtevnih procesih, da zagotovite skladnost z regulativnimi zahtevami.

Uvajati, usklajevati in nenehno izboljš evati standarde in najbolj š e prakse asepti č nih elektrarn ter vseh modalitet TRD (celi č ne in genske terapije, radioligandske terapije, ADC in nove biolo š ke entitete).

Biti ključ ni partner pri medfunkcijskih projektih, odpravljati tež ave in usklajevati dele ž nike glede pragmatič nih re š itev in standardov.

Mentorirati in razvijati čl lane TRD QA Sterile Operations Network ter naslavljanje kritič ne vrzeli v znanju.

Posvetujte se pri ocenjevanju in izbiri zunanjih izvajalcev glede aseptič ne ustreznosti, s č imer zagotovite integriteto zunanjih procesov.

About the Role

Major Accountabilities:

- Establish, lead, and continuously develop a TRD QA Sterile Operations Network, fostering accountability, learning, and collaboration.
- Provide specialist knowledge and guidance on sterile and low bioburden processes, ensuring compliance with regulatory requirements.
- Implement, harmonize, and continuously improve aseptic standards and best practices across TRD pilot plants and across all modalities (Cell and Gene Therapies, Radioligand Therapies, ADC, and New Biological Entities).
- Drive continuous improvement, knowledge transfer, and innovation in sterility assurance.
- Act as a key partner in cross-functional projects, troubleshooting issues and aligning stakeholders on pragmatic solutions and standards.
- Mentor and develop members of the TRD QA Sterile Operations Network, addressing critical skills gaps.
- Consult on the evaluation and selection of external contractors for aseptic appropriateness, ensuring integrity of outsourced processes.

Desired skills:

- Influence without authority in a matrix environment—build credibility, align stakeholders, and drive standards adoption.
- Proactive relationship-building—actively engage cross-functional partners to create momentum for change.
- Pragmatic risk-taking—balance diligence with smart, solution-oriented decision-making.
- Advanced problem-solving—lead troubleshooting and resolution across departmental boundaries.
- Effective communication—tailor messaging, negotiate, and handle pushback diplomatically.
- Political savvy—navigate informal networks and overcome barriers to secure a seat at the table.

Qualifications

- Advanced degree (PhD, MSc, or equivalent) in life sciences, pharmacy, or related field
- Extensive experience in sterile manufacturing, quality assurance, or related areas within the pharmaceutical/biotech industry
- Strong knowledge of aseptic processing, sterility assurance, and regulatory requirements (e.g., FDA, EMA, ICH)
- Proven track record in leading cross-functional teams or networks, ideally in a matrix environment
- Demonstrated ability to influence without authority and drive change across organizational boundaries
- Excellent problem-solving, communication, and stakeholder management skills
- Fluent in English; additional languages a plus

Benefits & Rewards

At Novartis, we're committed to reimagining medicine together - and rewarding the people who make it happen.

Expected Annual Base Salary Range for role: € 75,880 to € 140,920

The base salary offered is determined based on gender-neutral objectives, such as relevant skills, competencies and experience in accordance with the Novartis pay setting policy and upon joining Novartis will be reviewed periodically.

In addition to your base salary, you may be eligible for a performance-based bonus depending on certain performance parameters.

The rewards of being part of our team go far beyond base pay and incentives. We also offer a variety of competitive benefits in kind to help you thrive personally and professionally, such as insurance plans, retirement plans, wellbeing resources and global recognition programs. In addition, we provide

flexible and hybrid working options, where possible, and minimum 14 weeks paid parental leave.

Glavne odgovornosti:

Vzpostaviti, voditi in nenehno razvijati TRD QA Sterile Operations Network, kar spodbuja odgovornost, učenje in sodelovanje.

Nudite strokovno znanje in usmeritve o sterilnih in nizkobiološko zahtevnih procesih, da zagotovite skladnost z regulativnimi zahtevami.

Uvajanje, usklajevanje in stalno izboljševanje standardov in najboljše praks aseptičnih zdravlil v pilotnih obratih TRD in vseh modalitetah (celične in genske terapije, radioligandske terapije, ADC in nove biološke entitete).

Spodbujajte neprekinjeno izboljševanje, prenos znanja in inovacije na področju zagotavljanja sterilnosti.

Biti ključni partner pri medfunkcijskih projektih, odpravljati težave in usklajevati deležnike glede pragmatičnih rešitev in standardov.

Mentorirati in razvijati članice TRD QA Sterile Operations Network ter naslavljanje kritične vrzeli v znanju.

Posvetujte se pri ocenjevanju in izbiri zunanjih izvajalcev glede aseptične ustreznosti, s čimer zagotovite integriteto zunanjih procesov.

Želene veščine:

Vplivajte brez avtoritete v matriksnem okolju – gradite kredibilnost, uskladite deležnike in spodbujajte sprejemanje standardov.

Proaktivno gradnjo odnosov – aktivno vključevanje medfunkcijskih partnerjev za ustvarjanje zagona za spremembe.

Pragmatično sprejemanje tveganja – uravnotežite prizadevnost s pametnim, rešilno usmerjenim odločanjem.

Napredno reševanje problemov – vodenje odpravljanja težav in reševanje čez meje oddelkov.

Učinkovita komunikacija – prilagodite sporočila, pogajajte se in diplomatsko reševajte odpor.

Politična spretnost – krmarite po neformalnih mrežah in premagujte ovire, da si zagotovite sedež za mizo.

Kvalifikacije

Napredna stopnja (PhD, MSc ali ekvivalent) iz življenjskih ved, farmacije ali sorodnega področja

Obsežne izkušnje na področju sterilne proizvodnje, zagotavljanja kakovosti ali sorodnih področij v farmacevtski/biotehnoški industriji

Močno znanje o aseptični obdelavi, zagotavljanju sterilnosti in regulativnih zahtevah (npr. FDA, EMA, ICH)

Dokazana uspešnost pri vodenju medfunkcijskih ekip ali omrežij, idealno v matriksnem okolju

Dokazana sposobnost vplivanja brez avtoritete in spodbujanja sprememb preko organizacijskih meja

Odlične veščine reševanja problemov, komunikacije in upravljanja deležnikov

tekoče govori angleško; dodatni jeziki so plus

Koristi in nagrade

V Novartisusmo zavezani skupnemu preoblikovanju medicine – in nagrajevanju ljudi, ki jo uresničijo.

Pričakovana letna osnovna plača Razpon za delovno mesto: € 75.880 do € 140.920

Osnovna plača je določena glede na spolno nevtralne cilje, kot so relevantne veščine, kompetence in izkušnje v skladu s politiko plač Novartisa, ob vstopu v Novartis pa se redno pregleduje.

Poleg osnovne plače ste morda upravičeni do bonusa na podlagi uspešnosti, odvisno od določenih parametrov uspešnosti.

Nagrade, ki jih prinaša članstvo v naši ekipi, segajo daleč preko osnovne plače in spodbud. Ponujamo tudi različne konkurenčne ugodnosti v naravi, ki vam pomagajo uspevati osebno in poklicno, kot so zavarovalni načrti, pokojninski načrti, viri za dobro počutje in globalni programi priznanja. Poleg tega ponujamo prilagodljive in hibridne možnosti dela, kjer je mogoče, ter najmanj 14 tednov plačane starševskega dopusta.

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 \(PDF 30 MB\)](#)

Primary location salary range
€ 75,880.00 - € 140,920.00

部门
Development

Business Unit
Quality

地点

Slovenia

站点

Menge š

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 kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId:
"kalturaplayer6a9db0cd2dc24882216702", provider: { widgetId: "10m7rm1pm", partnerId:
"2076321", uiConfId: "55802022" }, playback: { autoplay: false, autopause: false, muted: false, loop:
false }, sources: { options: {}, startTime: 0 }, disableUserCache: "true", plugins: {}, sources: { options:
{}, startTime: 0 }, ui: { showCCButton: false, settings: { showQualityMenu: true, showSpeedMenu:
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
(kPlayer.plugins["download"]) { config.plugins.download = { disable: true }; } if
(kPlayer.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 (kPlayer.plugins["preventSeek"]) {
config.plugins.preventSeek = { preventSeekForward: false, preventSeek: false }; }
config.plugins.floating = { disable: true }; if (kPlayer.plugins["navigation"]) { config.plugins.navigation =
{ position: "right", expandMode: "over", expandOnFirstPlay: false, visible: false }; } if
(kPlayer.plugins["hotspots"]) { config.plugins["playkit-js-hotspots"] = { disable: true }; } if
(kPlayer.plugins["moderation"]) { config.plugins["playkit-js-moderation"] = { disable: true }; } if
(kPlayer.plugins["info"]) { config.plugins["playkit-js-info"] = { disable: true }; } if
(kPlayer.plugins["share"]) { config.plugins.share = { disable: true }; } config.ui.uiComponents = []; if
(kPlayer.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 } };
```

```
// Ensure the global player registry array always exists, regardless of embed type.  
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) }
```

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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