

Ekspert kakovosti II v tehni č nem razvoju biolo š kih zdravil (m/ ž /d) / Quality Manager (m/f/d)

Job ID
REQ-10087733

九月 23, 2026

Slovenia

摘要

Lokacija: Menges, Slovenija #onsite

Namen vloge:

Zagotavljanje strokovnega znanja, usmerjanja in podpore za zagotavljanje kakovosti operativnim dejavnostim v razvojnih in raziskovalnih organizacijah, da se zagotovi skladnost z veljavno regulativno zahtevo, postopki in standardi kakovosti podjetja Novartis.

Upravljaliti projekte, vklju č no z iniciativami Na č rta kakovosti, in procese, ki podpirajo cilje kakovosti, da zagotovijo njihovo skladnost s predpisi GxP.

Location: Menges, Slovenia #onsite

Role Purpose:

Provide quality assurance expertise, guidance and support to operational activities in development

and research organizations to ensure compliance with applicable regulatory requirements and Novartis procedures and quality standards.

Manage projects, including Quality Plan initiatives, and processes that support quality objectives to assure their compliance with GxP regulations.

About the Role

Glavne odgovornosti:

- Podpora vzdrževanju regulativno zahtevanih dokumentov za inšpekcijske preglede zdravstvenih organov ter pomoč pri upravljanju inšpekcij zdravstvenih organov. Podpirajte pripravo kakovostnih načrtov (in pregledajte druge načrte glede kakovosti in varnosti) za klinične programe.
- Podpirati pobude za ohranjanje ali izboljšanje kakovosti, uspešnosti in skladnosti operativnih dejavnosti, vključno z upravljanjem tveganj, poročanjem zdravstvenih organov, IT sistemi.
- Podprite pobude, osredotočene na izboljšanje kakovosti, procesov in skladnosti, vključno z prepoznavanjem priložnosti ter razvijajte strategije za izboljšanje kakovosti ob zagotavljanju skladnosti z regulativnimi zahtevami. Zagotovite, da so informacije, pridobljene med pobudami za kakovost in skladnost ter rezultati revizij in ocenjevanja, ocenjeni, da se prepoznajo morebitne regulativne, skladnostne in QA potrebe po usposabljanju.
- Pomagati pri prepoznavanju težav s kakovostjo ter pomagati pri preiskavah temeljnih vzrokov in podpirati razvoj načrtov korektivnih in preventivnih ukrepov (CAPA), vključno s spremljanjem statusa, da se zagotovi, da so težave rešene, dokončane in dokumentirane.
- Nuditi pomoč pri odpravljanju odstopanj, zagotoviti spremljanje in spremljanje povezanih korektivnih in preventivnih ukrepov.
- Upravljati in podpirati vidike kakovosti projektov in dejavnosti, vključno s tistimi, povezanimi s tretjimi osebami, analitskimi instrumenti, proizvodno opremo, načrti kakovosti, usposabljanjem, IT validacijami itd.
- Pregledujte in odobrite kakovostne rezultate za zagotovitev skladnosti (vključno s postopki, dokumentacijo, delom tretjih oseb, pogodbeniki, gradivom kliničnih preskušanj, komponentami, ocenami vrzeli).
- Prijavljanje težavnih primerov / neželjenih dogodkov / posebnih primerov, povezanih z izdelki Novartis, v 24 urah po prejemu.
- Distribucija marketinških vzorcev (kjer je to primerno).

Ključni kazalniki uspešnosti

- Sistem kakovosti grozdov je vzpostavljen in se nenehno posodablja, po potrebi pa se tveganja proaktivno prepoznajo in učinkovito zmanjšujejo.
- Število in resnost težav, ugotovljenih med notranjimi in zunanji revizijami.
- Dokazano/priznано vodja specifičnega GxP; zgodnje zunanje/industrijsko sodelovanje.
- Zadostno finančno znanje (npr. upravljanje stroškov, napoved proračuna itd.).
- Vzor kulture, vrednot in vedenj podjetja Novartis.

Koristi in nagrade

V Novartis smo zavezani skupnemu preoblikovanju medicine – in nagrajevanju ljudi, ki jo uresničijo. Pri čakovani letni osnovni plači ni razpon za delovno mesto: € 32,060 do € 59,540 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 članstva v naših ekipi segajo daleč preko osnovne plače in spodbud. Ponujamo tudi različne konkurenčne ugodnosti, ki vam pomagajo uspevati osebno in poklicno, kot so zavarovalni načrti, pokojninski načrti, viri za dobrobit in globalni programi priznanja. Poleg tega ponujamo, kjer je mogoče, prilagodljive in hibridne možnosti dela ter najmanj 14 tednov plačane starševskega dopusta.

Major Accountabilities:

- Support maintenance of the regulatory -required files for health authority inspections and assist with health authority inspection management
- Support generation of Quality Plans (and review other plans for quality/safety aspects) for clinical programs
- Support initiatives to maintain or improve quality performance and compliance of operational activities including risk management, health authority reporting, IT systems
- Support initiatives focused on quality, process and compliance improvement, including identification of opportunities and develop strategies aimed at improving quality while ensuring compliance with regulatory requirements
- Ensure information gained during quality and compliance initiatives, as well as audit and assessment results, are evaluated to identify any regulatory, compliance and QA training needs
- Aid in the identification of quality issues and assist with root cause investigations and support the development of corrective and preventative action plans (CAPA), including monitoring status to Ensure issues are addressed, completed and documented.
- Provide assistance in the remediation of deviations, Ensure follow up and monitoring of associated corrective and preventive actions.
- Manage and Support quality aspects of projects and activities, including those related to third parties, analytical instruments, manufacturing equipment, quality plans, training, IT validations, etc.
- Review and approve quality deliverables to ensure compliance (including procedures, records, third party work, contractors, clinical trial material, components, gap assessments)
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt
- Distribution of marketing samples (where applicable)

Key Performance Indicators:

- Clusters Quality System in place and continuously updated, as required risks proactively identified and effectively mitigated
- The number and severity issues identified during internal and external audits.
- Demonstrated/recognized leader of specific GxP; early external/industry engagement
- Sufficient financial knowledge (e.g., cost management, budget forecast, etc.)

- Role Model of Novartis culture, values & behaviours

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: € 32,060 to € 59,540

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.

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
€ 32,060.00 - € 59,540.00

部门
Development

Business Unit
Quality

地点
Slovenia

站点
Mengeš

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:
"kalturaplayer6abb0c39876f2982400536", 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:
```

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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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3. <mailto:diversity.inclusionslo@novartis.com>
4. <https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Menge/Ekspert-kakovo-sti-II-v-tehninem-razvoju-biolokih-zdravil--m--d---Quality-Manager--m-f-d-REQ-10087733-1>
5. <https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Menge/Ekspert-kakovo-sti-II-v-tehninem-razvoju-biolokih-zdravil--m--d---Quality-Manager--m-f-d-REQ-10087733-1>