NOVARTIS

Vodja validacij (m/ ž /d) / Validation Lead (m/f/d)

Job ID
REQ-10078184

十月 02, 2026

Slovenia

摘要

#LI-Hybrid
Location: Ljubljana, Slovenija
Relocation Support: This role is based in Ljubljana Slovenia. Novartis is unable to offer relocation support: please only apply if accessible.

Ste pripravljeni prevzeti klju č no vlogo pri oblikovanju prihodnosti ene najpomembnej š ih Novartisovih proizvodnih lokacij?

Na lokaciji Aseptika Ljubljana ustvarjamo strate š ko sredi š č e za lansiranje in proizvodnjo inovativnih asepti č nih zdravil, saj bo to edinstvena lokacija v Novartisovi svetovni mre ž i, kjer bodo na voljo vse klju č ne tehnologije za proizvodnjo asepti č nih zdravil. Pri nas boste imeli prilo ž nost soustvarjati re š itve, ki bodo pacientom po vsem svetu prina š ale nove mo ž nosti zdravljenja.

Kot del na š e ekipe boste sodelovali z vrhunskimi strokovnjaki iz Slovenije in mednarodnega okolja ter prispevali k postavljanju novih standardov odli č nosti v farmacevtski industriji. Va š e delo bo imelo neposreden vpliv na razvoj in dostopnost inovativnih terapij za paciente po vsem svetu, hkrati pa boste imeli prilo ž nost za strokovno rast v enem najbolj naprednih proizvodnih okolij v Novartisu.

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Are you ready to play a pivotal role in shaping the future of one of Novartis ' most strategic manufacturing sites?

At our Ljubljana Aseptic Manufacturing site, we are building a global center of excellence for the launch and production of innovative aseptic medicines. This unique site will be the only location within the Novartis network to bring together all core aseptic manufacturing technologies under one roof. Joining our team means helping to deliver breakthrough therapies that expand treatment possibilities for patients around the world.

As part of this exciting journey, you will collaborate with leading experts from Slovenia and across the global Novartis organization, driving innovation and setting new standards of excellence in pharmaceutical manufacturing. Your work will have a direct impact on the development, production, and accessibility of life-changing therapies, while providing exceptional opportunities for professional growth in one of the most advanced manufacturing environments at Novartis.

About the Role

Va š e klju č ne odgovornosti:

- Razvijanje in izvajanje strategije validacije procesov, č i š č enja, pakiranja in teko č ega preverjanja.
- Zagotavljanje skladnosti validacij z GMP, internimi predpisi, zakonodajo in standardi kakovosti.
- Vzpostavljanje in vzdr ž evanje glavnih na č rtov validacije ter spremljanje validacijskih statusov lokacije.
- Pripravljanje validacijskih protokolov in dokumentacije ter vodenje validacijskih aktivnosti.
- Svetovanje pri ocenjevanju tveganj in izvajanju validacijskih strategij za nove izdelke.
- Sodelovanje pri prenosih in lansiranjih izdelkov ter pripravi registracijske dokumentacije.
- Koordiniranje z oddelki za in ž eniring, IT, QC in AS&T pri kvalifikacijah in validacijah.
- Vodenje validacijskih sej in zastopanje lokacije v validacijski mre ž i.
- Skrb za usposabljanje in razvoj sodelavcev ter upravljanje u č nih na č rtov.
- Podpiranje pri izvajanju Novartisovih proizvodnih praks in zagotavljanje trajnostnega poslovanja.

Va š doprinos k delovnem mestu:

- Zaklju č ena visoko š olska izobrazba naravoslovne, farmacevtske ali tehni č ne smeri.
- Izku š nje z validacijo procesov, č i š č enja in pakiranja v reguliranem okolju (za ž eleno vsaj 5 let izku š enj).
- Dobro poznavanje zahtev dobre proizvodne prakse (GMP) in zakonodaje s podro č ja zdravil.
- Sposobnost priprave validacijske dokumentacije in vodenja validacijskih aktivnosti.
- Izku š nje s sodelovanjem z razli č nimi oddelki (npr. IT, QC, in ž eniring) pri validacijah.
- Sposobnost ocenjevanja tveganj in uporabe orodij za upravljanje tveganj.
- Aktivno znanje angle š kega jezika v pisni in ustni obliki, poznavanje lokalnega jezika

(sloven š č ina) je prednost.

Z izbranim kandidatom bomo sklenili delovno razmerje za **nedolo** č **en** č **as** poskusno dobo **6 mesecev.**

Ugodnosti in nagrajevanje:

Konkuren č en pla č ni paket, letni bonus, fleksibilen na č in dela z mo ž nostjo prilagajanja urnika in delom od doma, pokojninska shema, shema nagrajevanja in priznanja dose ž kov, raz š irjeni program promocije zdravja na podro č ju telesnega, du š evnega in fizi č nega po č utja (iniciativa Polni ž ivljenja), š tevilne prilo ž nosti za u č enje in razvoj.

Preberite na š priro č nik, da spoznate na č ine, s katerimi bomo spodbujali va š osebni in profesionalni razvoj: https://www.novartis.com/careers/benefits-rewards

Predani smo raznolikosti in vklju č **enosti:** Novartis si prizadeva ustvariti izjemno, vklju č ujo č e delovno okolje in oblikovanje raznolikih timov, saj ti predstavljajo na š e bolnike in skupnosti, ki jih oskrbujemo.

Pridru ž **ite se Novartisu:** Ni pravo delovno mesto za vas? Prijavite se v na š o bazo talentov, da ostanete v kontaktu z nami in se seznanite z ustreznimi kariernimi prilo ž nostmi takoj, ko se pojavijo: https://talentnetwork.novartis.com/network

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Become a key figure in ensuring robust processes, maintaining a constant state of validation, and continuously improving process performance, evaluated through statistical analysis of critical parameters in MS&T, as a Validation Lead (m/f/d). In this role, you will lead the development and implementation of validation strategies that form the foundation for safe, effective, and compliant manufacturing operations. You will take responsibility for the development, implementation, and execution of process validations, packaging validations, cleaning validations, and revalidations, in line with timelines and available resources. In doing so, you will ensure compliance with applicable legislation, good practices, internal regulations, quality standards, and regulatory agency requirements.

If you are passionate about working in a regulated environment where your expertise can truly make an impact - then this is the opportunity for you.

Key Responsibilities:

- Develop and execute validation strategies for processes, cleaning, packaging, and ongoing process verification.

- Ensure validation compliance with GMP, internal policies, legislation, and quality standards.
- Establish and maintain the site validation master plan and monitor validation status.
- Prepare validation protocols and documentation and lead validation activities.
- Advise on risk assessments and validation strategies for new product introductions.
- Participate in product transfers and launches and support registration documentation preparation.
- Coordinate with Engineering, IT, QC, and AS&T departments on qualifications and validations.
- Host validation board meetings and represent the site in the validation network.
- Support training and development of team members and manage training curricula.
- Support implementation of Novartis manufacturing practices and ensure business continuity.

What you will bring to the role:

- University degree in natural sciences, pharmacy, or technical field.
- Experience in process, cleaning, and packaging validation in a regulated environment.
- Strong knowledge of GMP requirements and pharmaceutical legislation.
- Ability to prepare validation documentation and lead validation activities.
- Experience collaborating with departments such as IT, QC, and Engineering.
- Risk assessment skills and familiarity with risk management tools.
- Fluent in English, both written and spoken. Fluent in Slovenian language is an advantage.

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.

Join our Novartis Network:
If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network

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
$0.00 - $0.00

部门
Operations

Business Unit
Production / Manufacturing

地点
Slovenia

站点
Ljubljana

Company / Legal Entity
SI19 (FCRS = SI019) Novartis farmacevtska proizvodnja d.o.o.

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work

No

var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId: "kalturaplayer6afb1e4778d5f661118190", 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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