

Expert Engineering/Inženir ekspert

Job ID
REQ-10081841

7月 16, 2026

Slovenia

摘要

Location: Menges, Slovenia #onsite

Your role

As an Engineering Expert, you will serve as a technical owner and subject matter expert for manufacturing equipment and systems throughout their entire lifecycle - from equipment selection and project implementation, through commissioning, qualification, operation, maintenance, continuous improvement and eventual replacement.

You will work closely with Manufacturing, QA, Automation, IT/OT, Validation and external suppliers to ensure equipment remains compliant, reliable, inspection-ready and capable of supporting clinical manufacturing needs.

This role is ideal for someone who enjoys combining engineering expertise, GMP compliance and hands-on technical problem solving in a fast-paced biopharmaceutical environment.

Klinična proizvodnja | Inženiring

V podjetju Novartis soustvarjamo prihodnost razvoja bioloških zdravil in klinične proizvodnje. BioCampus Mengeš se razvija v sodoben, integriran proizvodni center za klinično proizvodnjo, ki združuje aktivnosti Drug Substance in Drug Product v visoko avtomatiziranem okolju, skladnem z zahtevami GMP.

Z nadaljnjo rastjo in še večjo izkušnjo strokovnjaka za inženiring, ki bo imel pomembno vlogo pri zagotavljanju zanesljivega delovanja opreme, tehnične skladnosti ter trajnostnega upravljanja življenjskega cikla proizvodnih sredstev, ki podpirajo razvoj prebojnih terapij.

About the Role

Key responsibilities

- Act as technical owner for Drug Substance, Drug Product and supporting utility equipment throughout the entire asset lifecycle
- Manage equipment lifecycle activities including maintenance strategies, reliability improvements, spare parts management, obsolescence management and asset replacement planning
- Participate in capital investment projects and technical transfers, including URS development, design reviews, FAT/SAT execution, commissioning, IQ/OQ/PQ and system handover to operations
- Support change controls, investigations, deviations, CAPAs and periodic reviews associated with equipment and systems
- Troubleshoot complex equipment and process-related issues to minimize downtime and maximize operational performance
- Collaborate with suppliers and service providers to ensure long-term equipment sustainability and technical support
- Support regulatory inspections and internal quality assessments
- Contribute to continuous improvement initiatives focused on reliability, operational excellence and process efficiency
- Mentor and technically support engineers and technicians across multidisciplinary engineering activities

Equipment and technologies may include

- Bioreactors and cell culture systems
- Chromatography and purification systems
- Tangential Flow Filtration (TFF) and filtration skids
- Centrifuges
- Process vessels and preparation systems
- Clean utilities (WFI, clean steam, process gases)
- Isolators and aseptic processing technologies
- Robotic sterile filling lines

What you bring

- University degree in Mechanical Engineering, Electrical Engineering, Mechatronics, or a related discipline
- 3+ years of engineering experience, preferred within pharmaceutical, biotechnology, life sciences or other regulated industries
- Practical experience with commissioning, qualification, maintenance and lifecycle management of manufacturing equipment
- Strong troubleshooting and root cause investigation skills across mechanical, electrical and automated systems
- Experience working within GMP-regulated environments
- Ability to work independently while effectively collaborating across multidisciplinary teams
- Excellent communication skills and a proactive problem-solving mindset

Expected Annual Base Salary Range for role: € 27,510 to € 51,090

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.

Ključne odgovornosti

- Delovanje kot tehnični skrbnik opreme za Drug Substance, Drug Product in podporne utility sisteme skozi celoten življenjski cikel sredstev.
- Upravljanje aktivnosti življenjskega cikla opreme, vključno s strategijami vzdrževanja, izboljševanjem zanesljivosti, upravljanjem rezervnih delov, obvladovanjem zastarelosti komponent (obsolescence management) ter načrtovanjem zamenjav opreme.
- Sodelovanje pri investicijskih projektih in tehničnih prenosih, vključno s pripravo uporabniških zahtev (URS), pregledi projektnih rešitev, FAT/SAT aktivnostmi, zagoni, IQ/OQ/PQ kvalifikacijami ter predajo sistemov v obratovanje.
- Podpora postopkom sprememb (Change Control), preiskavam odstopanj, CAPA aktivnostim in periodičnim pregledom opreme ter sistemov.
- Odpravljanje zahtevnejših težav na področju opreme in procesov z namenom zmanjševanja izpadov ter izboljševanja operativne učinkovitosti.
- Sodelovanje z dobavitelji in servisnimi partnerji za zagotavljanje dolgoročne vzdržnosti opreme ter ustrezne tehnične podpore.
- Podpora regulatornim inšpekcijam in notranjim pregledom kakovosti.
- Prispevanje k iniciativam stalnih izboljšav na področju zanesljivosti, operativne odličnosti in učinkovitosti procesov.

- Mentoriranje ter tehniki na podpora inženirjem in tehnikom pri multidisciplinarnih inženirskih aktivnostih.

Oprema in tehnologije

Delo lahko vključuje naslednje tehnologije:

- Bioreaktorje in sisteme za celične kulture
- Kromatografske sisteme in sisteme za čiščenje produktov
- Sisteme tangencialne filtracije (TFF) in filtracijske skide
- Centrifuge
- Procesne posode in pripravljalne sisteme
- Sisteme čistih medijev (WFI, čista para, procesni plini)
- Izolatorje in aseptične proizvodne tehnologije
- Robotske sterilne polnilne linije

Kaj pričakujemo

- Univerzitetno izobrazbo s področja strojništva, elektrotehnike, mehatronike ali sorodnih tehničnih smeri.
- Zaželeno najmanj 3 let izkušenj na področju inženiringa, zaželeno v farmacevtski, biotehnološki ali drugi regulirani industriji.
- Praktične izkušnje z zagoni in kvalifikacijami, vzdrževanjem in upravljanjem življenjskega cikla proizvodne opreme.
- Dobro poznavanje tehničnih odpravljanih napak in iskanja vzrokov težav na mehanskih, električnih in avtomatiziranih sistemih.
- Izkušnje z delom v GMP reguliranem okolju.
- Sposobnost samostojnega dela in učinkovitega sodelovanja v multidisciplinarnih ekipah.
- Odlične komunikacijske sposobnosti ter proaktiven pristop k reševanju problemov.

Pričakovani letni osnovni plačnik razpon za delovno mesto: Dodajte celotno referenčno vrednost po delovnem dnevu, npr.: € 27,510 to € 51,090

Osnovna plačila 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 naših 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 plačanega 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
€ 27,510.00 - € 51,090.00

部门
Development

Business Unit
Development

地点
Slovenia

站点
Menge š

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:
"kalturaplayer6a9d74bb6bdf0026967985", 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 kalturadatalayer.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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