

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

Job ID
REQ-10062503

9月 29, 2025

Slovenia

摘要

#LI-Hybrid

Kot Ekspert kakovosti I (Senior Quality Manager) se pridru ž ite zelo povezani ekipi odli č nih ekspertov kakovosti, da skupaj z ostalimi ekipami v Razvoju biolo š kih zdravil Menge š zgradimo in za ž enemo v obratovanje edinstveno razvojno GMP proizvodno - razvojno sredi š č e Biocampus Menge š ! Z nove proizvodne lokacije bomo oskrbovali bolnike z inovativnimi zdravili v zgodnjih klini č nih š tudijah I in II.

Imeli boste tudi mo ž nost za samostojno vodenje ali podporo kompleksnim razvojnim projektom inovativnih biolo š kih molekul.

—

As a Senior Quality Manager, you will join a highly connected team of excellent quality experts to build and operationalize a unique GMP development and production center, Biocampus Menge š , together with other teams in the Development of Biological Medicines Menge š ! From the new production location, we will supply patients with innovative medicines in early clinical studies I and II.

You will also have the opportunity to independently lead or support complex development projects of innovative biological molecules.

About the Role

Vaš e ključ ne odgovornosti:

- Nuditi funkcionalno strokovno znanje na področju zagotavljanja kakovosti (QA) enoti in drugim oddelkom.
- Pisati, pregledovati, odločati o odobritvi in/ali izdaji GMP-relevantnih dokumentov in/ali povezanih orodij v skladu s področjem odgovornosti, da se zagotovi skladnost s cGMP in kakovostnimi dobavami projekta.
- Nuditi podporo QA za proizvodni proces zdravil (DP) in učinkovin (DS) v Biocampusu (npr. priprava glavnega poročila o seriji (mBR) in pregled izpolnjenih poročil o seriji (BR), ocene tveganja, kvalifikacija opreme,...).
- Podpirati funkcije projektnega vodenja kot član projektne ekipe.
- Nuditi podporo TRD linijskim funkcijam pri temah, povezanih z GMP, v skladu s področjem odgovornosti.
- Skrb za skladnost z notranjimi in zunanjimi smernicami glede kakovosti in varnosti (Priročnik kakovosti, regulativne smernice cGMP, smernice zdravstvenih organov, SOP-ji itd.).
- Odgovornost za osebni in strokovni razvoj.
- Druga opravila, določena med letnim procesom določanja ciljev in s KPI-ji.
- Druge naloge po navodilu nadrejenega in naloge na podlagi posebnega imenovanja.

Vaš doprinos k delovnem mestu:

- Visoko šolska ali univerzitetna izobrazba naravoslovne smeri (pogojeno z leti izkušenj).
- Minimalno 5 let delovnih izkušenj (v primeru visoko šolske izobrazbe) ali minimalno 3 leta delovnih izkušenj (v primeru univerzitetne izobrazbe) v QA ali tehničnih operacijah.
- Tekoče znanje angleščine (govorno in pisno). Zaželeno znanje lokalnega jezika.

Zaželene izkušnje:

- Izkušnje iz GMP okolja različnih procesov (proizvodnje, analitike, drugo).
- Projektno vodenje.

Z izbranim kandidatom bomo sklenili delovno razmerje za nedoločeno ~~as~~poskusno dobo 6 mesecev. Prijavo oddajte z življenjepisom v slovenskem in angleškem jeziku.

Ugodnosti in nagrajevanje:

Konkurenčni plačni paket, letni bonus, fleksibilen način dela z možnostjo prilagajanja urnika in delom od doma, pokojninska shema, shema nagrajevanja in priznanja dosežkov, razširjeni program promocije zdravja na področju telesnega, duševnega in fizičnega počutja (iniciativa Polni živiljenja), 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 vključnosti Novartis si prizadeva ustvariti izjemno, vključujoče delovno okolje in oblikovanje raznolikih timov, saj ti predstavljajo naše bolnike in skupnosti, ki jih oskrbujemo.

Dostop in prilagoditve: V Novartisu si prizadevamo k vključnosti oseb z invalidnostjo in zagotavljanju ustreznih prilagoditev delovnega okolja posameznikom z omejitvami. V kolikor zaradi bolezni ali invalidnosti potrebujete ustrezne prilagoditve v kateremkoli delu selekcijskega procesa oziroma potrebujete prilagoditve pri izvajanju osnovnih nalog na delovnem mestu, nam pišite na naslov diversity.inclusion slo@novartis.com in navedite, kakšne prilagoditve potrebujete ter vaše kontaktne podatke. Prosimo, vključite tudi podatek o številki razpisa, na katerega se prijavljate.

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 živiljenja pacientov. Ste pripravljeni ustvariti svetlejšo prihodnost skupaj z nami? <https://www.novartis.com/about/strategy/people-and-culture>

Pridružite se Novartisu Ni pravo delovno mesto za vas? Prijavite se v našo bazo talentov, da ostanete v kontaktu z nami in se seznanite z ustreznimi kariernimi priložnostmi takoj, ko se pojavijo: <https://talentnetwork.novartis.com/network>

—

Key Responsibilities:

- Provide QA functional expertise to Line Unit and other QA Units in area of responsibility.
- Write, review, decide on approval and/or release of GMP-relevant deliverables and or/ related tools as per area of responsibility in order to ensure compliance with cGMP and project quality deliverables.
- Provide Biocampus drug product and drug substance manufacturing process QA support (e.g. master batch record preparation, risk assessments, equipment qualification,...)
- Support Project management functions as a project team member.
- Provide support to TRD line functions in GMP related topics as per area of responsibility.
- Comply with internal and external guidelines regarding quality and safety (Quality Manual, regulatory cGMP guidelines, Health Authority guidance, SOPs etc.).
- Responsibility for personal and professional development.
- Other tasks determined during the annual objectives setting process and by KPIs.

- Other tasks as assigned by the supervisor, and tasks based on a specific appointment.

Essential Requirements:

- University degree in a natural science field (conditional on years of experience).
- Minimum 5 years of experience (in case of Bachelor degree) or minimum 3 years of experience (in case of Masters degree) in pharma quality or operations.
- Fluent English language skills (spoken and written). Knowledge of the local language is desirable.

Desirable Requirements:

- Experience in GMP environment of various processes (production, analytics, etc.).
- Project management.

We offer permanent employment with 6 months of probation period. Submit your application with the CV in Slovenian and English language.

Benefits and Rewards: Competitive salary, Annual bonus, Flexible working schedule, tailored to your needs, possibility to work from home, Pension scheme, Employee Recognition Scheme, Expanded program for the promotion of health in the field of physical, mental and social well-being (Well-being), Unlimited learning and development opportunities.

Read our handbook to learn about all the ways we 'll help you thrive personally and professionally:
<https://www.novartis.com/careers/benefits-rewards>

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.

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.

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>

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up:

<https://talentnetwork.novartis.com/network>

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <https://www.novartis.com/careers/benefits-rewards>

部门

Development

Business Unit

Innovative Medicines

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

[Apply to Job](#)

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.

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.



Job ID
REQ-10062503

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

[Apply to Job](#)

Source URL:

<https://www.novartis.com.cn/careers/career-search/job/details/req-10062503-ekspert-kakovosti-i-v-tehnicnem-razvoju-bioloskih-zdravil-mzd-senior-quality-manager-mfd>

List of links present in page

1. <https://www.novartis.com/careers/benefits-rewards>
2. <mailto:diversity.inclusionslo@novartis.com>
3. <https://www.novartis.com/about/strategy/people-and-culture>
4. <https://talentnetwork.novartis.com/network>
5. <https://www.novartis.com/careers/benefits-rewards>
6. <https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Menge/Ekspert-kakovo-sti-I-v-tehninem-razvoju-biolokih-zdravil--m--d----Senior-Quality-Manager--m-f-d-REQ-10062503-1>
7. <mailto:diversity.inclusionslo@novartis.com>
8. <https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Menge/Ekspert-kakovo-sti-I-v-tehninem-razvoju-biolokih-zdravil--m--d----Senior-Quality-Manager--m-f->

d-REQ-10062503-1