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

Job ID
REQ-10058482

7月 28, 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.

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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

Va š **e klju** č **ne odgovornosti:**

- Nuditi funkcionalno strokovno znanje na podro č ju zagotavljanja kakovosti (QA) enoti in drugim oddelkom.
- Pisati, pregledovati, odlo č ati o odobritvi in/ali izdaji GMP-relevantnih dokumentov in/ali povezanih orodij v skladu s podro č jem odgovornosti, da se zagotovi skladnost s cGMP in kakovostnimi dobavami projekta.
- Nuditi podporo QA za proizvodni proces zdravil (DP) in u č inkovin (DS) v Biocampusu (npr. priprava glavnega poro č ila o seriji (mBR) in pregled izpolnjenih poro č il o seriji (BR), ocene tveganja, kvalifikacija opreme,...).
- Podpirati funkcije projektnega vodenja kot č lan projektne ekipe.
- Nuditi podporo TRD linijskim funkcijam pri temah, povezanih z GMP, v skladu s podro č jem odgovornosti.
- Skrb za skladnost z notranjimi in zunanjimi smernicami glede kakovosti in varnosti (Priro č nik kakovosti, regulativne smernice cGMP, smernice zdravstvenih organov, SOP-ji itd.).
- Odgovornost za osebni in strokovni razvoj.
- Druga opravila, dolo č ena med letnim procesom dolo č anja ciljev in s KPI-ji.
- Druge naloge po navodilu nadrejenega in naloge na podlagi posebnega imenovanja.

Va š **doprinos k delovnem mestu:**

- Visoko š olska ali univerzitetna izobrazba naravoslovne smeri (pogojeno z leti izku š enj).
- Minimalno 5 let delovnih izku š enj (v primeru visoko š olske izobrazbe) ali minimalno 3 leta delovnih izku š enj (v primeru univerzitetne izobrazbe) v QA ali tehni č nih operacijah.
- Teko č e znanje angle š č ine (govorno in pisno). Za ž eleno znanje lokalnega jezika.

Za ž **elene izku** š **nje:**

- Izku š nje iz GMP okolja razli č nih procesov (proizvodnje, analitike, drugo).
- Projektno vodenje.

Z izbranim kandidatom bomo sklenili delovno razmerje za **nedolo** č **en** č **as** s poskusno dobo **6 mesecev.** Prijavo oddajte z ž ivljenjepisom v slovenskem in angle š kem jeziku.

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

Zakaj Novartis: Pomagati bolnikom in njihovim dru ž inam zahteva ve č 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 ž ivljenja pacientov. Ste pripravljeni ustvariti svetlej š o prihodnost skupaj z nami?
https://www.novartis.com/about/strategy/people-and-culture

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

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.

Dostop in prilagoditve: V Novartisu si prizadevamo k vklju č enosti 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 pi š ite na naslov diversity.inclusionslo@novartis.com in navedite, kak š ne prilagoditve potrebujete ter va š e kontaktne podatke. Prosimo, vklju č ite tudi podatek o š tevilki razpisa, na katerega se prijavljate.

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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
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

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Accessibility and accommodation

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List of links present in page

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