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

Job ID
REQ-10062511

11月 18, 2025

Slovenia

## 摘要

#LI-Hybrid

Lokacija / Location: Menge š , Slovenia

Kot Ekspert kakovosti II (Quality Manager) se pridru ž ite zelo povezani ekipi odli č nih ekspertov kakovosti. Va š a glavna naloga bo samostojno vodenje ali podpora kompleksnim razvojnim projektom inovativnih biolo š kih molekul s stali š č a zagotavljanja kakovosti, kot č lan CMC ekipe. Sodelovali boste tudi pri nekaterih QA aktivnosti pri vzpostavitvi Biocampusa Menge š .

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As a Quality Expert II (Quality Manager), you join a close-connected team of excellent quality experts. Your main task will be to independently manage or support complex development projects of innovative biological molecules from a quality assurance perspective, as a member of the CMC team. You will also be involved in some of the QA activities in the set-up of Biocampus Menge š .

## 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 narovoslovne 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 eljeno 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

**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.

**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

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**Key Responsibilities**:

- Provide functional expertise in Quality Assurance (QA) to the unit and other departments.
- To write, review, decide on approval and/or issue of GMP-relevant documents and/or associated tools in accordance with area of responsibility to ensure cGMP compliance and quality project deliverables.
- Provide QA support for the manufacturing process of Drugs (DP) and Drug Substances (DS) in Biocampus (e.g. preparation of Master Batch Report (mBR) and review of completed Batch Reports (BR), risk assessments, equipment qualification,...).
- Support project management functions as a member of the project team.
- Provide support to TRD line functions on GMP related topics in accordance with area of responsibility.
- To ensure compliance with internal and external quality and safety guidelines (Quality Manual, cGMP regulatory guidelines, health authority guidelines, SOPs, etc.).
- Responsibility for personal and professional development.
- Other tasks defined during the annual target setting process and by KPIs.
- Other tasks as directed by supervisor and by specific appointment.

**Essential Requirements:**

- A university or college degree in a natural science (years of experience required).
- Minimum 5 years of work experience (in case of university degree) or minimum 3 years of work experience (in case of university degree) in QA or technical operations.
- Fluency in English (spoken and written). Knowledge of the local language desirable.
- Preferable experience:
- Experience in GMP environment of different processes (production, analytics, other).
- 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.

**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

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Business Unit
Quality

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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