

Ekspert upravljanja kakovosti – razvoj (m/ž/d) / Development Quality Assurance Manager (m/f/d)

Job ID

REQ-10055107

Jun 27, 2025

Slovenia

Summary

#LI-Hybrid

Kot Ekspert upravljanja kakovosti v razvoju, boste odgovori za zagotavljanje nadzora kakovosti dejavnosti, ki se izvajajo v vseh enotah Novartisa v državi. Skrbeli boste, da se dejavnosti izvajajo v skladu z ustreznimi predpisi in smernicami za dobro klinično prakso (GCP) in dobro farmakovigilanco (GPvP). Dejavnosti v obsegu vključujejo, vendar niso omejene na: zagotavljanje, da so vzpostavljeni ustrezni sistemi in procesi za zaščito varnosti pacientov, pravic in dobrega počutja, integritete podatkov in nadzora kakovosti kliničnih in farmakovigilancijskih dejavnosti po potrebi, tako v pred, kot po tržnih okoljih.

Odgovorni boste tudi za zagotavljanje kakovosti in skladnosti razvojnih, globalnih in lokalnih medicinskih zadev (MA) ter komercialnih projektov, izdelkov in programov, usmerjenih k pacientom. Delovali boste v neposrednem sodelovanju z lokalnimi sodelavci za razvoj (operacije študij in lokacij, varnost pacientov in regulativne zadeve), medicinskimi zadevami in Novartis Country Quality (NCQ) oddelkom, z namenom zagotavljanja skladnosti z zahtevami Novartisa.

The Development Quality Assurance Manager is responsible for assuring quality oversight of activities undertaken in all Novartis entities in the country to ensure they are conducted in compliance with relevant Good Clinical Practice (GCP) and Good Pharmacovigilance Practice (GPvP) regulations and guidelines. Activities in scope include but may not be limited to assuring that adequate systems and processes are in place for the protection of patient safety, rights and well-being, data integrity, and quality oversight of Clinical and Pharmacovigilance activities as needed in both pre- and post- market settings.

You will be also responsible for assuring the quality and compliance of Development, Global and local Medical Affairs (MA) & Commercial patient-facing projects, products and programs. Operates in direct collaboration with local Development colleagues (Study and Site Operations, Patient Safety and Regulatory Affairs), Medical Affairs and Novartis Country Quality (NCQ) to ensure compliance to Novartis requirements and relevant HA regulations and guidance. Ensures implementation of the Novartis Quality Manual and Quality Management System in assigned country(ies) to achieve a high level of quality and compliance.

About the Role

Vaše ključne odgovornosti:

- Izvajanje, vzdrževanje in spremljanje lokalnega sistema kakovosti, da se zagotovi skladnost z

Novartisovimi globalnimi zahtevami in veljavnimi lokalnimi predpisi.

- Spremljanje rezultatov lokalnega načrta kakovosti (QP), povezanih z območji GCP in PV, s čimer se zagotovi usklajenost z globalnimi poglavji QP.
- Skrb za vzpostavljanje ustreznih sistemov usposabljanja za GCP, GPvP in druge ustrezne razvojne dejavnosti, pri čemer je pomembno vzdrževanje dokumentacije, pripravljene za inšpekcijske preglede.
- Spodbujanje kliničnih preiskav / PV QA na državni ravni in zagotavljanje izvajanja robustnih načrtov korektivnih in preventivnih ukrepov (CAPA).
- Spremljanje lokalnih sistemov kakovosti, procesov in ključnih kazalnikov kakovosti (KQI) za proaktivno prepoznavanje potencialnih tveganj kakovosti in sodelovanje s poslovnimi partnerji pri njihovem reševanju.
- Vodenje in podpora inšpekcijskim pregledom zdravstvenega organa GCP in GPvP (HA), zagotavljanje pravočasnih predložitvev odgovorov lokalnemu HA in dokončanje CAPA.
- Partnerstvo z lokalnimi in globalnimi razvojnimi ekipami pri izvajanju in spremljanju revizij kliničnega razvoja in dejavnosti PV ter zagotavljanje izvajanja robustnih korektivnih in preventivnih ukrepov.
- Zagotavljanje kakovosti, ki je potrebna za kvalifikacijo in spremljanje/upravljanje dejavnosti tretjih oseb s klinično/medicinsko ali PV komponento.

Vaš doprinos k delovnem mestu:

- Univerzitetna izobrazba naravoslovne smeri.
- Več kot 5 let izkušenj v farmacevtski industriji na ustreznem področju, kot so zagotavljanje kakovosti, regulativne zadeve, farmakovigilanca ali neposredno povezano področje, po možnosti z najmanj 3 leti izkušenj v kliničnem razvoju.
- Tekoče znanje slovenskega in angleškega jezika.

Z izbranim kandidatom bomo sklenili delovno razmerje za **določen čas** s poskusno dobo **6 mesecev**. Prijavo oddajte z življenjepisom v angleškem jeziku.

Ugodnosti in nagrajevanje: Konkurenčen 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 življenja), 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>

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 življenja 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>

Predani smo raznolikosti in vključenosti: Novartis si prizadeva ustvariti izjemno, vključujoče delovno okolje in oblikovanje raznolikih timov, saj ti predstavljajo naše bolnike in skupnosti, ki jih oskrbujeemo.

Dostop in prilagoditve: V Novartisu si prizadevamo k vključenosti 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.

Key responsibilities:

- Oversee implementation, maintenance, and monitoring of the local Quality System to ensure compliance with Novartis global requirements and applicable local regulations.
- Support and monitor implementation of the local Quality Plan (QP) deliverables related to GCP and PV areas, ensuring alignment with global QP chapters.
- Ensure adequate training systems are in place for GCP, GPvP, and other relevant Development activities, maintaining inspection-ready documentation.
- Drive Clinical/PV QA investigation activities at the country level and ensure implementation of robust Corrective and Preventive Action (CAPA) plans.
- Monitor local Quality System, processes, and Key Quality Indicators (KQIs) to proactively identify potential quality risks and collaborate with business partners to address them.
- Provide leadership and support for GCP and GPvP Health Authority (HA) inspections, ensuring timely submission of responses to local HA and completion of CAPAs.
- Partner with local and global Development teams in the execution and follow-up of audits on clinical development and PV activities, ensuring robust corrective and preventive actions are implemented.
- Execute QA activities required for the qualification and monitoring/governance of third party activities with a clinical/medical or PV component.

Essential Requirements:

- University degree in natural sciences.
- More than 5 years experience in the pharmaceutical industry in a relevant field such as quality assurance, regulatory affairs, pharmacovigilance or a directly related area, preferably with a minimum of 3 years experience in clinical development.
- Fluent in Slovenian and English language.

We offer **temporary employment for 1 year** with **6 months** of probation period. Submit your application with the CV in 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.inclusion_slo@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>

Division

Development

Location

Slovenia

Site

Ljubljana

Company / Legal Entity

SIA0 (FCRS = CH024) Novartis Pharma Services

Functional Area

Quality

Job Type

Full time

Employment Type

Temporary (Fixed Term)

Shift Work

No

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