NOVARTIS

Ekspert zagotavljanja kakovosti - skladnost (m/ž/d) / QA Compliance Expert (m/f/d)

Job ID
REQ-10083030
июл 13, 2026
Словения
Available in: English

Сводка

#LI-Hybrid
Location: Ljubljana, Slovenia
Relocation Support: This role is based in Ljubljana, Slovenia. Novartis is unable to offer relocation support: please only apply if accessible.

Želite s svojim delom neposredno prispevati k varnosti pacientov in kakovosti izdelkov? Pridružite se Novartisu kot Ekspert upr. kakovosti – skladnost in prevzemite pomembno vlogo pri zagotavljanju kakovosti ter skladnosti za področje medicinskih pripomočkov. Na tem dinamičnem delovnem mestu boste odgovorni za ključne aktivnosti na področju kakovosti, povezane z dokumentacijo, transferji, reklamacijami, spremembami in regulatornimi zahtevami, ter sodelovali z različnimi deležniki znotraj organizacije. Če vas motivira delo v hitro spreminjajočem se okolju, učinkovito obvladujete več prioritet hkrati ter vas veseli pridobivanje novih znanj, vas vabimo k prijavi.

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Ready to make a real impact on patient safety and product quality? Join Novartis as a QA Compliance Expert and play a key role in ensuring quality and compliance across our Medical Devices portfolio. In this dynamic role, you will oversee critical quality activities related to documentation, product transfers, complaints, changes, and regulatory compliance while collaborating with diverse stakeholders across the organization. If you thrive in a fast-paced environment, enjoy managing multiple priorities, and are passionate about continuous learning and quality excellence, we would love to hear from you.

About the Role

Vaše ključne odgovornosti:

- Zagotavljanje skladnosti aktivnosti s trenutnimi dobrimi praksami in zahtevami glede integritete podatkov.
- Pregledovanje in odobravanje dokumentacije, sprememb, transferjev ter zapisov o kakovosti za medicinske pripomočke.
- Koordinacija aktivnosti, povezanih z reklamacijami, raziskavami, korektivnimi in preventivnimi ukrepi.
- Podpora pri inšpekcijskih pregledih, presojah in regulatornih ocenah ter zagotavljanje stalne pripravljenosti na inšpekcijske preglede.
- Pregledovanje in odobravanje dokumentacije, ki jo zahtevajo regulatorni organi za posamezne trge.
- Spremljanje kazalnikov kakovosti ter prepoznavanje priložnosti za nenehne izboljšave in operativno odličnost.
- Sodelovanje z medfunkcijskimi ekipami pri zagotavljanju skladne implementacije zahtev kakovosti in skladnosti.
- Delovanje kot zaupanja vreden strokovnjak za kakovost ter spodbujanje kulture skladnosti, odgovornosti in kakovosti.

Vaš doprinos k delovnem mestu:

- Visokošolska stopnja izobrazbe farmacevtske, biološke, kemijske, mikrobiološke ali druge ustrezne naravoslovne smeri.
- Najmanj 3 leta delovnih izkušenj na področju proizvodnje, razvoja, kakovosti ali drugega reguliranega okolja.
- Aktivno znanje angleškega jezika; tekoče znanje slovenskega jezika predstavlja prednost.
- Visoka stopnja samoiniciativnosti, odgovornosti ter sposobnost samostojnega organiziranja dela in prioritet.
- Sposobnost učinkovitega obvladovanja več nalog hkrati v dinamičnem delovnem okolju.
- Želja po učenju ter usmerjenost v nenehne izboljšave in kakovost.

Zaželene izkušnje:

- Poznavanje zakonodaje in zahtev kakovosti na področju medicinskih pripomočkov, vključno z ISO 13485.
- Izkušnje z medicinskimi pripomočki, kombiniranimi izdelki ali drugimi reguliranimi izdelki za področje zdravstva.

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

Nagrajevanje:

V Novartisu smo zavezani k soustvarjanju prihodnosti medicine ter priznavanju in nagrajevanju ljudi, ki to omogočajo.

Pričakovani letni osnovni razpon plače za delovno mesto:

32.060,00 - 59.540,00 EUR

Osnovna plača se določa na podlagi vnaprej opredeljenih in transparentnih kriterijev, kot so relevantne veščine, kompetence in izkušnje, ne glede na spol, ter v skladu z Novartisovo politiko določanja plač. Po zaposlitvi v Novartisu se plača periodično pregleda v skladu z internimi akti in postopki.

Plačna enakost je temeljno načelo naše kadrovske politike in odraža našo zavezo k ustvarjanju raznolikega, pravičnega in vključujočega okolja, ki vse zaposlene obravnava dostojanstveno in spoštljivo, kot je opredeljeno v našem Kodeksu etike.

Poleg osnovne letne bruto plače so zaposleni upravičeni tudi do spodaj navedenih ugodnosti:

- **Letni bonus,** ki pripada vsakemu zaposlenemu: 9% letne plače. (STI, change in regards of level)
- **Regres za dopust**: Leta 2025 je znašal 2.496 € (neto). Za leto 2026 znaša 2.678,28 € (neto).
- **Nagrada za poslovno uspešnost**: Leta 2025 je znašala 2.538,64 € (bruto), skupaj z zimskim regresom.
- **Prostovoljno dodatno pokojninsko zavarovanje**: Novartis v Sloveniji zagotavlja prostovoljno dodatno pokojninsko zavarovanje (5,844 % bruto izplačila, letno omejeno na 3.054,65 €).
- **Zavarovanje: Dodatno nezgodno zavarovanje:** V času zaposlitve pri Novartisu je zaposleni 24/7 zavarovan za primer smrti ali invalidnosti, ki bi bila posledica nezgode. **Zavarovanje – Specialisti**: Kolektivno zdravstveno zavarovanje, ki omogoča hitrejši dostop do specialističnih zdravstvenih storitev pri Zavarovalnici Triglav d.d. za vas in vaše družinske člane.
- **Care Connect:** Program, ki ponuja zaupno, osebno podporo za vaše duševno zdravje in dobro počutje s pomočjo terapij, svetovanj, orodij in še mnogo več.
- Ostale ugodnosti v skladu z zakonom in kolektivno pogodbo: **Prevoz, prehrana ter ostali dodatki.**

Preberite brošuro in izvedite več o našem sistemu nagrajevanja: https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf

Opomba: Ugodnosti se lahko razlikujejo glede na državo ter so skladni z lokalno zakonodajo, vključno z določili kolektivnih pogodb. Celovit pregled vašega paketa prejemkov, vključno z morebitnimi relevantnimi določbami kolektivne pogodbe, ki veljajo za vašo delovno mesto glede na lokacijo zaposlitve in delodajalca Novartis, vam bo posredovan v okviru nadaljnjih korakov zaposlitvenega postopka.

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 oskrbujemo.

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

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Key Responsibilities:

- Ensure compliance with current Good Practices and data integrity requirements
- Review and approve documentation, changes, transfers, and product quality records for Medical Devices.
- Coordinate quality activities related to product complaints, investigations, corrective actions, and preventive actions.
- Support inspections, audits, and regulatory assessments while maintaining a state of inspection readiness.
- Review and approve country-specific documentation required by health authorities and regulatory bodies.
- Monitor quality performance metrics and identify opportunities for continuous improvement and operational excellence.
- Collaborate with cross-functional teams to ensure compliant implementation of quality and compliance requirements.
- Act as a trusted quality partner, driving ownership, compliance, and quality culture across the organization.

Essential Requirements:

- University degree in Pharmacy, Biology, Chemistry, Microbiology, or another relevant scientific discipline.
- Minimum 3 years of experience in manufacturing, development, quality, or a related regulated environment.
- Proficiency in English; fluent Slovenian is considered an advantage.
- Strong sense of ownership, self-initiative, and ability to independently organize priorities and workload.
- Ability to manage multiple tasks simultaneously and perform effectively in a fast-paced environment.
- Resilience, learning agility, and commitment to continuous improvement and quality excellence.

Desirable Requirements:

- Knowledge of Medical Device Regulations and quality requirements, including ISO 13485.
- Experience with medical devices, combination products, or other regulated healthcare products.

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

Rewards:

At Novartis, we're committed to reimagining medicine together - and rewarding the people who make it happen.

Expected Annual Base Salary Range for role:

32.060,00 - 59.540,00 EUR

The 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.

Pay equity is a fundamental principle of our employment policy and reflects our commitment to create a diverse, equitable and inclusive environment that treats all employees with dignity and respect, as outlined in our Code of Ethics.

In addition to your base salary, you will be eligible for benefits listed below:

- **Annual bonus for all employees:** 9% of annual base salary. (STI, change in regards of level)
- **Holiday allowance:** In 2025 it amounted to €2,496 (net). For 2026 it amounts to €2,678.28 (net).
- **Yearly performance-based bonus:** In 2025 it amounted to €2,538.64 (gross), including the winter allowance.
- **Voluntary supplementary pension insurance:** Novartis in Slovenia provides voluntary supplementary pension insurance (5.844% of gross salary, capped annually at €3,054.65).
- **Insurance: Additional accident insurance:** During employment at Novartis, the employee is insured 24/7in the event of death or disability resulting from an accident. **Specialist insurance:** Group health insurance providing faster access to specialist healthcare services at Triglav Health Insurance Companyd.d. for you and your family members.
- **Care Connect:** A program offering confidential, personalized support for mental health and well-being through therapy, counselling, tools, and more.
- Other benefits in accordance with legislation and collective agreements: **Transportation, meal allowance, and other supplements.**

Read our brochure to learn more about our global total rewards offering:https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf

Note: Benefits and compensation may vary by country and are subject to local legal requirements, including provisions of collective bargaining agreements where applicable. A full overview of your compensation package, including any relevant collective bargaining agreement details applicable to your role based on your employment location and Novartis employer entity, will be communicated separately to you during the application process.

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.

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
€32,060.00 - €59,540.00
Дивизион
Operations
Business Unit
Quality
Место
Словения
Сайт
Ljubljana
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

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.

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Apply to Job

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