

# Specialist upravljanja kakovosti za področje upravljanja kakovosti prostorov, opreme, HVAC sistemov in medijev (m/ž/d) / Quality specialist for premises, equipment, HVAC systems and media (m/f/d)

Job ID

REQ-10008088

Juli 16, 2024

Slowenien

## Zusammenfassung

Kot Specialist upravljanja kakovosti za področja upravljanja kakovosti prostorov, opreme, HVAC sistemov in medijev boste igrali ključno vlogo pri zagotavljanju skladnosti vseh treh proizvodnih lokacij v Novartis d.o.o.. Sodelovali boste tudi s številnimi Novartisovimi obrati po celem svetu s katerimi sodelujemo na področju kakovosti za laboratorijske in proizvodne aktivnosti. Iščemo kandidate, ki so navdušeni nad iskanjem rešitev, postavljanjem sistema kakovosti in dejstvom, da so v ospredju inovacij na področju skladnosti proizvodnih in laboratorjskih procesov. Če ste navdušeni nad priložnostjo, da delate v dinamičnem mednarodnem okolju vas spodbujamo, da se prijavite in se nam pridružite. S svojim znanjem in željo po napredku nam boste pomagali da zagotavljamo kakovost, skladnost in odličnost pri delovanju naših laboratorijev, proizvodnih enot v Novartisu ter sodelovanju z zunanjimi partnerji v farmacevtski industriji in s strokovnjaki v agencijah za zdravila številnih držav po svetu. As a Quality specialist for premises, equipment, HVAC systems and media, you will play a crucial role in ensuring compliance across all three production locations at Novartis LLC. You will also collaborate with numerous Novartis facilities worldwide that we partner with in the realm of quality for laboratory and production activities. We are seeking candidates who are enthusiastic about finding solutions, establishing a quality system, and being at the forefront of innovation in the compliance of production and laboratory processes. If you are excited about the opportunity to work in a dynamic international environment, we encourage you to apply and join us. With your knowledge and desire for progress, you will help us ensure the quality, compliance, and excellence in the operation of our laboratories, Novartis production units, and collaboration with external partners in the pharmaceutical industry, as well as with experts in drug agencies from various countries around the world.

## About the Role

### Vaše ključne odgovornosti:

- Zagotavljanje, da so vse dejavnosti v skladu s trenutnimi dobrimi praksami (cGxP), ter v skladu z integriteto podatkov. Podpora pri inšpekcijskih nadzorih in presojah. Sodelovanje pri izvedbi internih presoj.
- Razvoj internega sistema kakovosti v skladu s farmacevtsko zakonodajo, dobrimi farmacevtskimi praksami in

Novartisovimi standardi kakovosti. Sodelovanje pri pripravi operativnih postopkov, pregledovanje in odobritev operativnih postopkov za relevantno področje.

- Razvoj, implementacija in zagotavljanje standardov kakovosti za opremo, medije in HVAC sisteme za zagotavljanje ustrezne kvalitete zraka v GMP prostorih.
- Podpora pri investicijskih projektih, sodelovanje pri pripravi, pregled in odobritev relevantne projektne dokumentacije.
- Pregledovanje in odobritev sprememb.
- Podpora pri preiskavi odstopov, upravljanje s korektivnimi in preventivnimi ukrepi.

#### **Vaš doprinos k delovnem mestu:**

- Visokošolska stopnja izobrazbe farmacevtske, kemijske, biotehnološke, strojne ali druge ustrezne smeri.
- Aktivno znanje slovenskega jezika.
- Aktivno znanje angleškega jezika.
- Poznavanje orodja Microsoft Office.
- Zaželene delovne izkušnje s področja proizvodnje, razvoja ali druge strokovne izkušnje s področja kakovosti.

Z izbranim kandidatom bomo sklenili delovno razmerje za **določen čas** s poskusno dobo **6 mesecov**.

Prijave z življenjepisom v slovenskem in angleškem jeziku lahko oddate preko spletne povezave.

#### **Zakaj Novartis?**

Naš namen je soustvarjati medicino za izboljšanje in podaljševanje življenja ljudi, naša vizija pa je postati najbolj cenjeno in zaupanja vredno farmacevtsko podjetje na svetu. Kako lahko to dosežemo? S pomočjo naših ljudi. Prav naši sodelavci nas vsak dan spodbujajo, da dosežemo svoje ambicije. Postanite del te misije in se nam pridružite! Več na spodnji povezavi: <https://www.novartis.com/about/strategy/people-and-culture>

#### **Kaj nudimo:**

Konkurenčen plačni paket, letni bonus, fleksibilen način dela, z možnostjo prilagajanja urnika in delom od doma, pokojninsko shemo, shemo nagrajevanja in priznanja dosežkov, razširjeni program promocije zdravja na področju telesnega, duševnega in družbenega počutja (Polni življenja) ter dogodke, neomejene priložnosti za učenje in razvoj.

#### **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.

#### **Pridružite se naši mreži Novartis:**

V kolikor se ne prepoznate v zgornjem opisu delovnega mesta, vas vabimo, da se vpišete na spodnji povezavi v Novartisovo bazo talentov saj lahko tako vašo vlogo upoštevamo za podobne pozicije v prihodnosti: <https://talentnetwork.novartis.com/network>

#### **Key Responsibilities:**

- Ensuring that all activities comply with current good practices (cGxP) and data integrity requirements.
- Support for inspections and audits. Participation in the execution of internal audits.
- Participation in development and maintenance of the internal quality system in accordance with pharmaceutical legislation, GMP and Novartis Quality Standards. Participation in the preparation of operational procedures, review and approval of operational procedures in the relevant area.
- Development, implementation and assurance of quality standards for equipment, media and HVAC systems to ensure adequate air quality in GMP areas.
- Support for investment projects, participation in the preparation, review and approval of relevant project documentation.
- Review and approval of changes.
- Support for investigating deviations, managing corrective and preventive actions.

### **Essential Requirements:**

- University degree in pharmacy, chemistry, biotechnology or other equivalent natural science degree.
- Fluent in English and Slovene.
- Knowledge of Microsoft Office.
- Preferred experience in production, development or other quality functions on expert position.

We offer a temporary employment for one year with 6 month of probation period.

You are kindly invited to submit your application in English and Slovenian language, including CV.

### **Why Novartis?**

Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: <https://www.novartis.com/about/strategy/people-and-culture>

### **You'll receive:**

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, 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.

### **Join our Novartis Network:**

If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here:

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

**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>

Abteilung  
Operations  
Business Unit  
Innovative Medicines  
Ort  
Slowenien  
Website  
Ljubljana  
Company / Legal Entity  
SI19 (FCRS = SI019) Novartis farmacevtska proizvodnja d.o.o.  
Functional Area  
Quality  
Job Type  
Full time  
Employment Type  
Temporary (Fixed Term)  
Shift Work  
No  
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## 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](mailto: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.

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

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