

Vodja Kakovosti ESO Končni izdelki (m/ž/d) / Quality ESO FDF Head (m/f/d)

Job ID
REQ-10085863
сен 10, 2026
Словения

Сводка

#LI-Hybrid
Lokacija/Location: Ljubljana, Slovenia

Vodenje in usmerjanje zaposlenih za zagotavljanje kakovosti ESO organizacije za končne izdelke pri vseh s kakovostjo povezanih zadevah, ter skrb za to, da so vsi vidiki operativnega poslovanja v skladu s trenutno veljavnimi načeli dobre proizvodne prakse (cGMP), zakonskimi predpisi in Novartisovim priročnikom za kakovost ter politiko družbe Novartis, vključno z Novartisovimi standardi kakovosti in storitev za kupce v skladu z zakonodajo, internimi predpisi, dobrimi praksami in poslovnimi cilji.

The Quality ESO FDF Head provides leadership and managing Quality Assurance Managers for ESO Quality in all quality related matters. Ensuring that all aspects of the operational business comply with cGMP legal and regulatory requirements and the Novartis Quality Manual and Policies, in accordance with the law, internal regulations, Good Practices, and business objectives. Responsibility for the leadership and development of associates.

About the Role

Vaše ključne odgovornosti:

- Upravljanje, podpora in nadzor tretjih oseb ter imetnikov licenc pri izvajanju in vzdrževanju lokalnih sistemov kakovosti, zagotavljanju virov ter spremljanju učinkovitosti.
- Spremljanje najnovejših zahtev zdravstvenih organov, trendov, tehnologij, postopkov in sistemov ter zagotavljanje skladnosti z zahtevami dobre proizvodne prakse.
- Upravljanje in podpora pri reševanju kakovostnih in tehničnih vprašanj pri zunanjih dobaviteljih v skladu z Novartisovimi in globalnimi standardi.
- Zagotavljanje priprave, vzdrževanja, rednega pregleda in upoštevanja sporazumov o zagotavljanju kakovosti, vključno z jasno opredeljenimi vlogami, odgovornostmi in zahtevami vseh vključenih strani.
- Določanje strategije kakovosti, načrtovanja kakovosti in upravljanja tveganj kakovosti za področje zunanje oskrbe, vključno z ocenjevanjem tveganj, CAPA ukrepi in zmanjševanjem nesprejemljivih tveganj.
- Zagotavljanje učinkovitega pregleda, stopnjevanja in reševanja kritičnih vprašanj kakovosti, vključno z reklamacijami, odpoklici, ponaredki, nepravilnostmi glede stabilnosti in drugimi odstopanji.
- Zagotavljanje zastopnosti kakovosti v procesih upravljanja zunanjih dobaviteljev in projektih, kot so prenos, lansiranje, skrbni pregledi ter priprava na inšpekcijske preglede zdravstvenih organov.
- Vodenje, razvoj in zagotavljanje usposobljenosti timov, spremljanje ključnih kazalnikov uspešnosti, vzdrževanje sodelovanja z internimi funkcijami ter spodbujanje pozitivnih odnosov z dobavitelji in poslovnimi partnerji

Vaš doprinos k delovnem mestu:

- Visokošolska stopnja izobrazbe ali doktorat s področja bioloških znanosti, farmacije, medicine ali druge ustrezne smeri.
- Aktivno znanje angleškega jezika.
- Poznavanje orodja Microsoft Office.
- Najmanj 5 let izkušenj na področju farmacevtske industrije.
- Izkušnje na področju zagotavljanja kakovosti, kontrole kakovosti, registracije zdravil ali proizvodnje.
- Izkušnje na drugem sorodnem področju se prav tako upoštevajo.

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:

- Slovenija: 46.900 – 87.100 €

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: 12% letne plače.
- **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 Novartis 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>

Major Accountabilities:

- Manage, support, and supervise Third Parties and Licensees in implementing and maintaining local Quality Management Systems, ensuring adequate resources, performance monitoring, and compliance with Novartis requirements.
- Maintain up-to-date knowledge of Health Authority requirements, industry trends, technologies, processes, systems, cGMP standards, and provide scientific and technical expertise on quality systems.
- Manage and support the resolution of quality and technical issues at Third Parties and Licensees, including complaints, recalls, counterfeits, product tampering, stability failures, investigations, CAPA plans, and timely escalation of critical issues.
- Create, maintain, review, and ensure compliance with Quality Assurance Agreements, clearly defining roles, responsibilities, and requirements for all parties involved in product supply.
- Define and implement quality strategy, quality planning, Quality Risk Management, KPIs, corrective actions, supplier oversight processes, and harmonized QA approaches across external suppliers, sites, and platforms.
- Represent QA in External Supplier Governance Boards and projects such as transfers, launches, due diligence, supplier readiness for Health Authority inspections, and ensure communication with internal functions including Legal, Regulatory CMC, Drug Regulatory Affairs, and GQO.
- Build, lead, and develop strong teams, ensure adequate trained resources, promote company vision and values, maintain positive supplier and business partner relationships, and support personal and professional development of associates.
- Manage HSE, environmental sustainability, and supplier assurance activities, including due diligence, regulatory monitoring, supplier risk assessments, continuous improvement programs, green economy initiatives, emissions and water compliance, best practice sharing, policy support, and collaboration with external stakeholders.

Obligatory Requirements:

- University degree or doctorate in biological sciences, pharmacy, medicine, or another relevant field.
- Fluency in English.
- Proficiency in MS Office.
- Minimum 5 years of experience in the pharmaceutical industry.
- Experience in quality assurance, quality control, drug registration, or manufacturing.
- Experience in another relevant or related field is also considered.

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:

- Slovenia: €46.900 – 87.100

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:** 12% of annual base salary.
- **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 24/7 in 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 Company d.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](https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf) 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
€46,900.00 - €87,100.00
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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