NOVARTIS

Višji ekspert upravljanja kakovosti – skladnost (m/ž/d) / Regulatory CMC Facilitator (m/f/d)

Job ID
REQ-10077823
май 15, 2026
Словения

Сводка

#LI-Hybrid
Lokacija: Mengeš, Slovenia
Interni naziv pozicije / Internal job title: Višji ekspert upravljanja kakovosti – skladnost / Senior QA Compliance Expert
Relocation Support: This role is based in Mengeš, Slovenia. Novartis is unable to offer relocation support: please only apply if accessible.

Ste pripravljeni na karierno priložnost, kjer bo vaš prispevek ključen pri uvajanju inovativnih zdravil na trg? Na našem oddelku za kakovost – skladnost, male molekule, iščemo strokovnjaka za upravljanje kakovosti, ki bo s svojim znanjem in izkušnjami povezoval in usklajeval regulativne CMC aktivnosti, povezane z lansiranjem zdravil ter aktivnostmi po njihovi odobritvi. Če vas veseli delo, ki neposredno vpliva na pravočasno dostopnost naprednih terapij ter zagotavljanje najvišjih standardov kakovosti, vas vabimo, da se nam pridružite in pustite svoj pečat.

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Are you ready for a career opportunity where your contribution plays a key role in bringing innovative medicines to market? Within our Quality – Compliance, Small Molecules department, we are looking for a Quality Management expert who will leverage their expertise to coordinate and align CMC regulatory activities related to product launches and post-approval processes. If you are motivated by work that enables timely patient access to advanced therapies while upholding the highest quality standards, we invite you to join us and make your mark.

About the Role

Vaše ključne odgovornosti:

- Delovati kot osrednja kontaktna oseba in strokovni svetovalec za globalno CMC regulativno obveščenost na lokaciji.
- Tesno sodelovati z Global Regulatory CMC ter spremljati in uvajati nove regulativne zahteve, strategije in trende.
- Izvajati neodvisne predhodne ocene zahtevkov za spremembe ter potrjevati ustrezno klasifikacijo kategorije I ali II.
- Zagotavljati pravilnost, popolnost in pravočasnost regulativno relevantnih informacij v zahtevkih za spremembe.
- Podpirati lokacijo pri razvoju učinkovitih strategij nadzora sprememb z večjim vplivom na produkte ali lokacije.
- Omogočati pripravo visokokakovostne CMC dokumentacije in modulov v skladu z dogovorjenimi CMC strategijami.
- Usposabljati in razvijati sodelavce glede regulativnih vidikov upravljanja sprememb ter krepiti kulturo skladnosti.

Vaš doprinos k delovnem mestu:

- Univerzitetna izobrazba farmacevtske, biološke, kemijske, mikrobiološke ali druge ustrezne naravoslovne smeri.
- Aktivno znanje angleškega jezika.
- Najmanj dve leti delovnih izkušenj na področju proizvodnje, razvoja ali kakovosti v reguliranem okolju.
- Dobro poznavanje lokalnih in globalnih regulativnih zahtev ter postopkov za nove kemične enote (NCE) in upravljanje življenjskega cikla izdelkov.
- Odlične komunikacijske in pogajalske sposobnosti ter sposobnost strateškega razmišljanja v kompleksnem okolju.
- Dobro poznavanje orodij Microsoft Office, projektnega dela ter sistemov za upravljanje dokumentacije, z visoko sposobnostjo učenja novih orodij.

Z izbranim kandidatom bomo sklenili delovno razmerje za **nedoločen 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, možnost vključitve v kolektivno zdravstveno zavarovanje, shema nagrajevanja in priznanja dosežkov, razširjeni program promocije zdravja na področju fizičnega in duševnega dobrega počutja ter delovne obremenitve (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

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:

- Act as the primary contact and expert advisor for global CMC regulatory intelligence at the site.

- Collaborate closely with Global Regulatory CMC to monitor and implement new regulatory requirements and strategies.
- Perform independent pre-assessments of change requests and confirm appropriate Category I or II classification.
- Ensure accuracy, completeness, and timeliness of regulatory-relevant information within change documentation.
- Support the site in developing effective change control strategies with broader product or site impact.
- Enable timely preparation of high-quality CMC documentation and modules aligned with agreed CMC strategies.
- Train and develop site colleagues on regulatory change management to strengthen compliance capabilities.

Essential Requirements:

- University degree in pharmacy, biology, chemistry, microbiology, or another relevant life science discipline.
- Proficient command of the English language.
- At least two years of professional experience in manufacturing, development, or quality within a regulated environment.
- Solid knowledge of local and global regulatory requirements, including submission processes for new chemical entities (NCE) and product lifecycle management.
- Strong communication and negotiation skills combined with strategic thinking in a cross-functional setting.
- Proficiency in Microsoft Office tools, project-based work, and document management systems, with a strong ability to learn new tools quickly.

We offer **permanent employment** 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, possibility of joining collective health insurance scheme, Employee Recognition Scheme, Expanded program for the promotion of health in the field of physical and mental well-being and managing workload (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.

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)

Дивизион
Operations
Business Unit
Quality
Место
Словения
Сайт
Mengeš
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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