

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

Job ID  
REQ-10077823  
May 15, 2026  
LOC\_SI

## 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, projektne delo 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 življenje), 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 Novartis cenimo sodelovanje, podporo in navdihanje drug drugega za razvoj prebojnih terapij, ki spreminjajo življenje 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.

## Role Requirements

**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 \(PDF 30 MB\)](#)

Division

DIV\_TO

Business Unit

Quality

Location

LOC\_SI

Site

Mengeš

Company / Legal Entity

SI19 (FCRS = SI019) Novartis farmacevtska proizvodnja d.o.o.

Functional Area

FCT\_QA

Job Type

Full time

Employment Type

Regular

Shift Work

No

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