

Ekspert upravljanja kakovosti – skladnost (m/ ž /d) / QA Compliance Expert (m/f/d)

Job ID
REQ-10050696

5月 06, 2025

Slovenia

摘要

Si želite izzivov na svoji karierni poti in aktivno sodelovati pri postavitvi novega aseptičnega proizvodnega obrata?

Pridružite se naši ekipi kot Ekspert upravljanja kakovosti – skladnost, kjer boste med drugim odgovorni za usklajevanje, usmerjanje in podporo pri pripravi regulatorne dokumentacije za vloge pri zdravstvenih organih, podpirali lokacijo pri učinkovitem nadzoru sprememb ter delovali kot kontaktna oseba za regulatorne vsebine.

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Are you striving for new challenges in your career path and want to actively participate in the establishment of a new aseptic production facility?

Join our team as a QA Compliance Expert, where you will be responsible for coordinating, guiding and providing support in the preparation of regulatory documentation for applications to health

authorities, supporting the site in efficient change control and acting as a point of contact for regulatory content.

About the Role

Va š e klju č ne odgovornosti:

- Izvajanje dejavnosti v skladu z dobrimi praksami, podpora pri validacijah, organizacija pregleda kakovosti ter usposabljanje ekipe.
- Dejavnosti v okviru upravljanja dobaviteljev, priprava in usklajevanje korektivnih ukrepov, pregled nadzora in odobritev sprememb ter lokalni nadzor nad skladnostjo podatkov.
- Upravljanje kakovosti procesa, pregled in odobritev QP deklaracij, spremljanje kazalnikov uspe š nosti in vzdr ž evanje prijav in certifikatov za lokalne zdravstvene oblasti.
- Komunikacija z zdravstvenimi oblastmi in izvajanje optimizacije procesov.
- Sodelovanje pri razvoju sistema kakovosti ter upravljanje korektivnih in preventivnih ukrepov.
- Pregled in odobritev dokumentacije, zagotavljanje spro š č anja serij izdelkov v skladu z zakonodajo in vsemi relevantnimi predpisi.
- Usklajevanje, usmerjanje in podpora pri pripravi regulatorne dokumentacije za vloge pri zdravstvenih organih.
- Kontaktna oseba za regulatorne vsebine.

Va š doprinos k delovnem mestu:

- Visoko š olska stopnja izobrazbe farmacevtske, biolo š ke, kemijske, mikrobiolo š ke ali druge ustrezne naravoslovne smeri.
- Minimalno 3 leta delovnih izku š enj na podro č ju proizvodnje, razvoja ali druge strokovne izku š nje na podro č ju kakovosti.
- Napredna uporaba Officeovih orodij.
- Aktivno pisno in govorno znanje angle š kega in lokalnega jezika.
- Dobro poznavanje smernic GMP in ustrezne zakonodaje.

Z izbranim kandidatom bomo sklenili delovno razmerje za nedolo č en č asposkusno dobo 6 mesecev.

Prijavo oddajte z ž ivljenjepisom v slovenskem in angle š kem jeziku.

Kaj nudimo:

Konkuren č en pla č ni paket, letni bonus, fleksibilen na č in dela, z mo ž nostjo prilagajanja urnika in delom od doma, pokojninsko shemo, shemo nagrajevanja in priznanja dose ž kov, raz š irjeni program promocije zdravja na podro č ju telesnega, du š evnega in dru ž benega po č utja (Polni ž ivljenje) ter dogodke, neomejene prilo ž nosti za u č enje in razvoj.

Predani smo raznolikosti in vključnosti

Novartis si prizadeva ustvariti izjemno, vključujoče delovno okolje in oblikovanje raznolikih timov, saj ti predstavljajo naše bolnike in skupnosti, ki jih oskrbujemo.

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Key Responsibilities:

- Performing activities in accordance with good practices, providing support in validations, organizing quality review and training the team.
- Activities related to supplier management, preparation and coordination of corrective actions, control review and approval of changes, and local compliance data oversight.
- Quality process management, review and approval of QP declarations, monitoring performance indicators, and maintaining applications and certificates for local health authorities.
- Communicating with health authorities and implementing process optimizations. Involvement in the development of the quality system and management of corrective and preventive actions.
- Review and approval of documentation, ensuring release of product batches in accordance with legislation and all relevant regulations.
- Coordination, guidance and support in the preparation of regulatory documentation for applications to health authorities.
- Point of contact for regulatory content.

Essential Requirements:

- Bachelor's degree level of education in pharmaceutical, biological, chemical, microbiological or other relevant natural science fields.
- Minimum 3 years of work experience in production, development or other professional quality-related experience.
- Advanced use of Office tools.
- Active writing and speaking knowledge of English and the local language.
- Good knowledge of GMP guidelines and relevant legislation.

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

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 (Wellbeing), 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>

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>

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <https://www.novartis.com/careers/benefits-rewards>

部门
Operations

Business Unit
Innovative Medicines

地点
Slovenia

站点
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

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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.inclusionslo@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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