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

Job ID
REQ-10050696
May 06, 2025
Slovenia

Summary

Si želite novih 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

Vaše ključne 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 uspešnosti in vzdrževanje 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 sproščanja 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.

Vaš doprinos k delovnem mestu:

- Visokošolska stopnja izobrazbe farmacevtske, biološke, kemijske, mikrobiološke ali druge ustrezne naravoslovne smeri.
- Minimalno 3 leta delovnih izkušenj na področju proizvodnje, razvoja ali druge strokovne izkušnje na področju kakovosti.
- Napredna uporaba Officeovih orodij.
- Aktivno pisno in govorno znanje angleškega in lokalnega jezika.
- Dobro poznavanje smernic GMP in ustrezne zakonodaje.

Z izbranim kandidatom bomo sklenili delovno razmerje za **nedoločen čas** s poskusno dobo **6 mesecev.**

Prijavo oddajte z življenjepisom v slovenskem in angleškem jeziku.

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.

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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

Division
Operations
Business Unit
Innovative Medicines
Location
Slovenia
Site
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
Apply to Job

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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