Vodja upravljanja kakovosti - operacije (m/ ž /d) / QA Operations Lead (m/f/d)

Job ID
REQ-10039990

Feb 11, 2025

Slovenia

Summary

JOB SUMMARY:

#LI-Onsite ALI #LI-Hybrid ALI #LI-Remote.

Kot Vodja upravljanja kakovosti - operacije boste zagotavljali vodstvo in usmerjali vodje zagotavljanja kakovosti v vseh zadevah, povezanih s kakovostjo, in zagotavljali, da so vsi vidiki operativnega poslovanja. Odgovorni boste za zagotavljanje skladnosti s standardi cGxP za izdelke v okviru podro č ja odgovornosti -razvoj, prenos in tr ž ene.-in izdaje izdelkov. Zagotavljali boste usmerjanje, podporo in vodenje ekipam na podro č ju odgovornosti v skladu z zakonom, internimi predpisi, dobrimi praksami in poslovnimi cilji. Odgovorni boste za stro š kovno u č inkovitost oddelka, zagotavljanje in izvajanje strokovnih znanj in ve š č in ter optimizacijo procesov. Pripomogli boste k vodenju in razvoju.

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We are seeking a QA Operations Lead. In this role, you will be providing Leadership and manage

Quality Assurance Managers in all quality related matters and to ensure that all aspects of the operational business. You will be responsible to ensure compliance to cGxP standards for products within area of responsibility (during development, transfer, and commercialization) and product release. You will provide guidance, support and leadership to teams within area of responsibility in accordance with the law, internal regulations, good practices and business objectives. You will be responsible for the cost efficiency of the department, provision and implementation of expert knowledge and skills, and process optimization. You will provide leadership and development of associates.

About the Role

Va š **e klju** č **ne odgovornosti**

- Priprava in sodelovanje pri revizijah in in š pekcijskih pregledih dobre prakse.
- Nadzor nad postopki v Kakovosti na lokacijah.
- Pregled in odobritev proizvodnega poro č ila.
- Sodelovanje pri razvoju, implementaciji in nadzoru sistema kakovosti v skladu s slovensko in evropsko zakonodajo, FDA, mednarodnim svetom za usklajevanje tehni č nih zahtev glede zdravil, Konvencijo o farmacevtski in š pekciji in Novartisovimi standardi.
- Spodbujanje optimizacije procesov, nenehnih izbolj š av, operativne odli č nosti, inovacij, proaktivna skrb za skladnost.
- Vodenje strate š kih dejavnosti, projektov, odlo č itev, zagotavljanje najsodobnej š ih proizvodnih in laboratorijskih procesov.
- Zagotavljanje spro š č anja serij izdelkov v skladu s slovensko zakonodajo, predpisi, ki veljajo v Evropski uniji in trgov na katere se zdravilo spro š č a, z vsemi internimi predpisi v dru ž bi Novartis in pogodbami s partnerji.

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 5 let delovnih izku š enj na podro č ju kakovosti, razvoja ali proizvodnje ali na primerljivih delovnih mestih
- Dobro poznavanje smernic cGMP.
- Dobre vodstvene sposobnosti in ozadje pri upravljanju virov / skupin.
- Dobro znanje pisnega in govornega angle š kega in lokalnega jezika

Z izbranim kandidatom bomo sklenili delovno razmerje za **nedolo** č **en** č **as** s poskusno 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 ivljenja) ter dogodke, neomejene prilo ž nosti za u č enje in razvoj.

Predani smo raznolikosti in vklju č **enosti**

Novartis si prizadeva ustvariti izjemno, vklju č ujo č e delovno okolje in oblikovanje raznolikih timov, saj ti predstavljajo na š e bolnike in skupnosti, ki jih oskrbujemo.

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Key Responsibilities:

- Preparation and collaboration in GxP audits in inspections.
- Oversight of Quality Operations across site.
- Master Batch Record (MBR) review, approval and product release.
- Ensure production and laboratory's GxP compliance and execution of activities in accordance with Slovenian, EU laws, Food and Drug Administration (FDA), International Council for Harmonisation Technical Requirements for pharmaceuticals for Human Use (ICH), The Pharmaceutical Inspection Convention (PIC) regulations and Novartis standards.
- Drive process optimization, continuous improvement, operational excellence, innovation, proactive compliance.
- Involved in strategic activities, projects, decision, assuring state of the art manufacturing and testing equipment and processes.
- Ensure release of product batches in accordance with Slovenian, EU laws, markets where product batches are released, internal Novartis standards and contracts with partners.

Essential Requirements:

- University degree in pharmacy, biology, chemistry, microbiology other equivalent natural or engineering science degree
- Minimum 5 years of experience in quality, development or manufacturing or on comparable positions
- Solid knowledge of cGMP guidelines.
- Strong leadership skills and background in managing resources/teams.
- Fluent English and local language, written and spoken.

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

部門
Operations

部門
Innovative Medicines

国
Slovenia

勤務地
Ljubljana

Company / Legal Entity
SI19 (FCRS = SI019) Novartis farmacevtska proizvodnja d.o.o.

Functional Area
Quality

職種
Full time

雇用形態
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.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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Apply to Job.

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5. mailto:diversity.inclusionslo@novartis.com
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