

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 področja odgovornosti - razvoj, prenos in tržene.-in izdaje izdelkov. Zagotavljali boste usmerjanje, podporo in vodenje ekipam na področju odgovornosti v skladu z zakonom, internimi predpisi, dobrimi praksami in poslovnimi cilji. Odgovorni boste za stroškovno učinkovitost oddelka, zagotavljanje in izvajanje strokovnih znanj in veščin ter optimizacijo procesov. Pripomogli boste k vodenju in razvoju.

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

Vaše ključne odgovornosti:

- Priprava in sodelovanje pri revizijah in inšpekcijskih pregledih dobre prakse.
- Nadzor nad postopki v Kakovosti na lokacijah.
- Pregled in odobritev proizvodnega poročila.
- Sodelovanje pri razvoju, implementaciji in nadzoru sistema kakovosti v skladu s slovensko in evropsko zakonodajo, FDA, mednarodnim svetom za usklajevanje tehničnih zahtev glede zdravil, Konvencijo o farmacevtski inšpekciji in Novartisovimi standardi.
- Spodbujanje optimizacije procesov, nenehnih izboljšav, operativne odličnosti, inovacij, proaktivna skrb za

skladnost.

- Vodenje strateških dejavnosti, projektov, odločitev, zagotavljanje najsodobnejših proizvodnih in laboratorijskih procesov.
- Zagotavljanje sproščanja serij izdelkov v skladu s slovensko zakonodajo, predpisi, ki veljajo v Evropski uniji in trgov na katere se zdravilo sprošča, z vsemi internimi predpisi v družbi Novartis in pogodbami s partnerji.

Vaš doprinos k delovnem mestu:

- Visokošolska stopnja izobrazbe farmacevtske, biološke, kemijske, mikrobiološke ali druge ustrezne naravoslovne smeri
- Minimalno 5 let delovnih izkušenj na področju 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 angleškega in lokalnega jezika

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

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>

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

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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.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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5. mailto:diversity.inclusion_slo@novartis.com
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