

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

Job ID
REQ-10069041
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Словения

Сводка

#LI-Hybrid
Location: Ljubljana, Slovenia

Predstavljajte si, da imate ključno vlogo pri vzpostavljanju kakovosti v novi aseptični proizvodnji v Sloveniji – obratu, ki uvaja najvišje standarde farmacevtske tehnologije in odpira novo poglavje v lokalni farmacevtski industriji.

Kot Vodja upravljanja kakovosti - operacije boste usmerjali operativne QA aktivnosti v proizvodnji, gradili kulturo kakovosti, oblikovali učinkovite procese ter zagotavljali, da življenjsko pomembna zdravila varno, skladno in pravočasno prispejo do bolnikov.

Vaše odločitve bodo sooblikovale stabilen zagon komercialne proizvodnje in dolgoročno operativno odličnost. Pri tem boste sodelovali z visoko motiviranimi strokovnjaki v dinamičnem, globalnem okolju, ki spodbuja inovacije, učenje in profesionalno rast.

Imagine stepping into a pivotal role in shaping quality standards within a new aseptic manufacturing facility in Slovenia—an operation introducing the highest levels of pharmaceutical technology and opening a new chapter in the local pharmaceutical industry.

As a QA Operations Lead, you will steer operational QA activities on the shop floor, build a strong quality culture, design effective processes, and ensure that life saving medicines reach patients safely, compliantly, and on time.

Your decisions will directly contribute to a stable commercial launch and long term operational excellence. You will collaborate with highly motivated professionals in a dynamic, global environment that fosters innovation, learning, and continuous professional growth.

About the Role

Vaše ključne odgovornosti:

- **Zagotavljanje skladnosti vseh aktivnosti z veljavnimi cGxP standardi** ter skrb za dosledno in pravilno izvajanje kakovostnih procesov na lokaciji.
- **Vodenje in podpora pri GxP presojah ter inšpekcijah regulatornih organov** vključno s pripravo dokumentacije in koordinacijo vseh aktivnosti na lokaciji.
- **Vodenje ekipe upravljanja kakovosti – operacije na lokaciji** z odgovornostjo za pravočasne, strokovne in skladne odločitve na področju QA.
- **Pregled in odobritev glavnih proizvodnih zapisov (Master Batch Records - MBR)** ter zagotavljanje njihove pravilnosti, sledljivosti in skladnosti z regulativnimi zahtevami.
- **Koordinacija sproščanja izdelkov** v skladu z globalnimi in lokalnimi regulativami, internimi postopki ter pričakovanji trga.
- **Spodbujanje operativne odličnosti** z uvajanjem najboljših praks, optimizacijo procesov ter krepitevijo kulture nenehnih izboljšav.
- **Učinkovito upravljanje operativnih stroškov oddelka za upravljanje kakovosti – operacij** ter aktivno iskanje priložnosti za racionalizacijo procesov brez vpliva na skladnost ali kakovost.

Vaš doprinos k delovnem mestu:

- Univerzitetna izobrazba iz farmacije, biologije, kemije, mikrobiologije ali druge ustrezne naravoslovne oziroma tehniške smeri.
- Najmanj 5 let izkušenj na področju kakovosti, proizvodnje ali primerljivih delovnih mest.
- Odlično poznavanje cGxP, EU/FDA regulative in mednarodnih standardov.
- Dokazane vodstvene sposobnosti ter izkušnje z razvojem ekip.
- Sposobnost vodenja presoj, inšpekcijskih pregledov in procesov sproščanja izdelkov.
- Tekoče znanje angleškega jezika.

Z izbranim kandidatom bomo sklenili delovno razmerje za **nedoločen čas** s poskusno dobo **6 mesecev**. Prijavo oddajte z življenjepisom v slovenskem in 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 življenja), številne 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.

Zakaj Novartis: Pomagati bolnikom in njihovim družinam zahteva več kot le inovativno znanost. Potrebna je skupnost zavzetih ljudi, kot ste vi.

V Novartisu cenimo sodelovanje, podporo in navdihovanje drug drugega za razvoj prebojnih terapij, ki spreminjajo življenja pacientov.

Ste pripravljeni ustvariti svetlejšo prihodnost skupaj z nami? <https://www.novartis.com/about/strategy/people-and-culture>

Pridružite se Novartisu: Ni pravo delovno mesto za vas? Prijavite se v našo bazo **1/6** tov, da ostanete v kontaktu z nami in

se seznanite z ustreznimi kariernimi priložnostmi takoj, ko se pojavijo:

Key Responsibilities

- **Ensure compliance with all activities in line with applicable cGxP standards** and oversee the consistent and correct execution of quality processes at the site.
- **Lead and support GxP audits and inspections by regulatory authorities** including preparation of documentation and coordination of all site activities.
- **Lead the Quality Operations team at the site** with responsibility for timely, expert, and compliant decision-making within QA.
- **Review and approve Master Batch Records (MBR)** and ensure the accuracy, traceability, and regulatory compliance of production documentation.
- **Coordinate product release** in accordance with global and local regulations, internal procedures, and market expectations.
- **Drive operational excellence** by implementing best practices, optimizing processes, and strengthening a culture of continuous improvement.
- **Effectively manage operational costs within Quality Operations** and proactively identify opportunities for process optimization without compromising compliance or quality.

Key Qualifications

- University degree in Pharmacy, Biology, Chemistry, Microbiology, or equivalent natural or engineering science.
- Minimum 5 years of experience in Quality, Manufacturing, or comparable positions.
- Strong understanding of cGxP, EU/FDA regulations, and international standards.
- Demonstrated leadership and team development skills.
- Ability to manage audits, inspections, and product release processes.
- Fluent proficiency in English.

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

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 \(PDF 30 MB\)](#)

Дивизион

Operations

Business Unit

Quality

Место

Словения

Сайт

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

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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