NOVARTIS

Site Quality Head (m/f/d) / Vodja kakovosti (m/ž/d)

Job ID
REQ-10067249
Apr 01, 2026
LOC_SI

About the Role

This role can be performed in English, and we welcome applications from international candidates. Relocation support may be available for the selected candidate.

Key Responsibilities:

- Lead the Site Quality organization and ensure robust oversight of all GxP functions.
- Act as Technical Responsible Person (Qualified Person) when required by regulatory standards.
- Develop and implement site quality risk assessments and compliance strategies.
- Ensure adherence to cGxP, data integrity, and eCompliance requirements across operations.
- Drive talent agenda through recruitment, training, coaching, and performance management.
- Foster diversity and deploy career paths and succession plans for site and unit.
- Guarantee associates are GMP-qualified before performing independent tasks.
- Maintain inspection readiness and lead quality aspects of crisis management.
- Assume delegated decision-making responsibilities under on-call management framework.

Essential Requirements:

- Degree-qualified in Pharmacy, Chemistry, Microbiology, or another relevant life sciences discipline.
- 8+ years of Extensive experience in pharmaceutical manufacturing, with a strong background in quality leadership across sterile production, quality assurance, quality systems, or related functions.
- Deep expertise in Aseptic and Sterile manufacturing is essential, including strong knowledge of aseptic processing, contamination control strategy, cleanroom operations, and the regulatory expectations associated with sterile products.
- Demonstrated ability to lead site quality activities in a highly regulated GMP environment, ensuring compliance, product quality, and continuous improvement.
- Proven success in building, leading, and developing high-performing teams, while fostering a strong quality culture, accountability, and collaboration across the site.
- Ability to operate effectively in complex and ambiguous environments, making sound decisions and setting clear direction in a dynamic business context.
- Solid track record in regulatory inspections and audit readiness, particularly with US FDA inspections; pre-approval inspection experience is highly desirable.
- Strong understanding of applicable regulatory requirements, internal quality standards, and industry best practices, with the ability to translate them into effective site-level quality oversight.
- Fluent in English, with strong written and verbal communication skills.

We offer permanent employment with 6 months of probation period.

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.

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Znanje slovenskega jezika za to vlogo ni zahtevano. Vabimo mednarodne strokovnjake z dobrim znanjem angleškega jezika, za izbranega kandidata pa je lahko na voljo tudi relokacijski paket.

Vaše ključne odgovornosti:

- Vodenje organizacije kakovosti lokacije.
- Implementiranje, zagotavljanje skladnosti in upravljanje praks, predpisanih v Novartisovem proizvodnem priročniku.
- Nadzorovanje kakovosti na področju GxP funkcij lokacije.
- Deluje kot tehnična odgovorna oseba lokacije (kvalificirana oseba).
- Zagotovljanje kakovosti izdelkov.
- Zagotavljanje regulatorne skladnosti in implementacija korporativnih standardov in določb kakovosti.
- Zagotavljanje statusa registracije pri lokalnih zdravstvenih organih (HA).
- Pripravljanje glavne datoteke lokacije za regulativne namene.
- Ocenjevanje tveganja kakovosti za lokacijo.
- Pregledovanje vodenja kakovosti.

Vaš doprinos k delovnem mestu:

- Univerzitetna izobrazba s področja farmacije, kemije, mikrobiologije ali druge ustrezne naravoslovne smeri.
- Najmanj 8 let obsežnih izkušenj v farmacevtski proizvodnji, z močnim ozadjem na področju vodenja kakovosti, vključno s sterilno proizvodnjo, zagotavljanjem kakovosti (QA), sistemi kakovosti ali sorodnimi funkcijami.
- Poglobljeno strokovno znanje s področja aseptične in sterilne proizvodnje, vključno z dobrim poznavanjem aseptičnih procesov, strategij za obvladovanje kontaminacije, delovanja čistih prostorov ter regulativnih zahtev, povezanih s sterilnimi proizvodi.
- Dokazana sposobnost vodenja aktivnosti kakovosti na lokaciji v strogo reguliranem GMP okolju, ob zagotavljanju skladnosti, kakovosti izdelkov in nenehnih izboljšav.
- Sposobnost učinkovitega delovanja v kompleksnih in nejasnih okoljih, sprejemanja premišljenih odločitev ter postavljanja jasne usmeritve v dinamičnem poslovnem kontekstu.
- Trdne izkušnje z regulativnimi inšpekcijami in pripravljenostjo na presoje, zlasti z inšpekcijami ameriške agencije FDA; izkušnje s predodobritvenimi inšpekcijami (Pre-Approval Inspections) so zelo zaželene.
- Dobro razumevanje veljavnih regulativnih zahtev, internih standardov kakovosti in najboljših praks v industriji ter sposobnost njihove učinkovite uporabe pri nadzoru kakovosti na ravni lokacije.
- Tekoče znanje angleškega jezika z dobrimi pisnimi in ustnimi komunikacijskimi sposobnostmi.

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

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.

Preberite naš priročnik, da spoznate načine, s katerimi bomo spodbujali vaš osebni in profesionalni razvoj: https://www.novartis.com/careers/benefits-rewards

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

Role Requirements

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)

Division
DIV_TO
Business Unit
Quality
Location
LOC_SI
Site
Ljubljana
Company / Legal Entity
SI19 (FCRS = SI019) Novartis farmacevtska proizvodnja d.o.o.
Functional Area
FCT_QA
Job Type
Full time
Employment Type
Regular
Shift Work
No
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