QA Compliance Lead / Vodja upravljanja kakovosti - skladnost

Job ID
REQ-10000613
Jul 01, 2024
Eslovenia

Resumen

We bring life-saving medicines to millions of people. We are at the crossroads of the latest advances in medical science and innovative digital technology. Everything we do is in line with our commitment to quality and to providing safe active substances for patients. Our commitment to quality is based on science, we innovate and our work is patient-centered. Whether you are involved in development, production, maintenance, compliance or analysis, your contribution will have a direct impact on patients. Without quality checks and quality assurance at all points in the process, we cannot reliably build patient trust. Do you value this mission? As QA Compliance Lead you will be responsible to provide successful strategic and managerial leadership for the sites or supplier in all quality related matters and to ensure that key aspects of the operational business comply with cGxP. 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.

About the Role

Key Responsibilities:

- Oversight and implementation of Quality Management System.
- Incident management.
- GxP Audit and inspection management.
- 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.
- Oversight of compliance of Operations across site.
- Involved in strategic activities, projects, decision, assuring state of the art manufacturing and testing equipment and processes.
- Ensure periodic site Quality reviews.
- Role model the culture aspiration of being Curious, Inspired and Un-bossed and ensure leaders and associates are aware and aligned on expectations and hold them accountable for success of culture journey.

Essential Requirements:

- University degree in pharmacy, biology, chemistry, microbiology other equivalent natural or engineering

science degree.
- Knowledge of Microsoft Office.
- Functional knowledge of English.
- Minimum 5 years of experience in quality, development or manufacturing or on comparable positions.

We offer **permanent employment**, with **6 months** of probation period.

You are kindly invited to submit your application in English language, including CV by **7th of June 2024.**

Why Novartis?
Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn morehere: https://www.novartis.com/about/strategy/people-and-culture

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 (Energized for Life), employment at Top SI Employer, 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.

Join our Novartis Network:
If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network

Opis delovnega mesta:

Prinašamo življenjsko pomembna zdravila milijonom ljudi. Smo na stičišču najnovejših dosežkov medicinske znanosti in inovativne digitalne tehnologije. Vse kar počnemo je usklajeno z našo zavezo h kakovosti in zagotavljanju varnih učinkovin za bolnike. Naša zaveza kakovosti temelji na znanosti, prinašamo inovativnost in naše delo je usmerjeno k bolnikom. Ne glede na to, ali sodelujete v razvoju, proizvodnji, vzdrževanju, skladnosti ali analizi, bo vaš prispevek neposredno vplival na bolnike. Brez preverjanja in zagotavljanja kakovosti v vseh točkah procesa ne moremo zanesljivo graditi zaupanja bolnikov. Vam to poslanstvo predstavlja vrednoto?

Kot Vodja upravljanja kakovosti – skladnost boste odgovorni za zagotavljanje uspešnega strateškega vodenja in upravljanja lokacije ali dobaviteljev za vse zadeve, ki so povezane s kakovostjo in zagotavljanje, da so ključni vidiki operativnega poslovanja skladni s trenutnimi dobrimi praksami. Zagotavljali boste smernice, podporo in vodenje tima na svojem področju odgovornosti skladno z zakonodajo, internimi smernicami, dobrimi praksami in poslovnimi cilji.

Vaše ključne odgovornosti:

- Nadzor in izvajanje sistema vodenja kakovosti.

- Obvladovanje incidentov.
- Vodenje revizij GxP in inšpekcijskih pregledov.
- 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.
- Nadzor nad skladnostjo dejavnosti na lokacijah.
- Vodenje strateških aktivnosti, projektov, odločitev, zagotavljanje najsodobnejših proizvodnih in laboratorijskih procesov.
- Zagotavljanje rednih pregledov kakovosti na lokaciji.
- Biti vzor na področju kulture vedoželjnosti, navdahnjenosti, so-vodenja (opolnomočenja) in zagotavljanje, da so vodje in sodelavci seznanjeni s pričakovanji. Medsebojno usklajevanje ter prevzemanje odgovornosti za uspeh na področju skupne kulture.

Vaš doprinos k delovnem mestu:

- Univerzitetna stopnja izobrazbe farmacevtske, biološke, kemijske, mikrobiološke ali druge ustrezne naravoslovne smeri.
- Aktivno znanje angleškega jezika.
- Poznavanje orodja Microsoft Office.
- Minimalno 5 let delovnih izkušenj na področju kakovosti, razvoja ali proizvodnje ali na primerljivih delovnih mestih.

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

Prijave z življenjepisom v angleškem in slovenskem jeziku lahko oddate najkasneje do **7.6.2024** preko spletne povezave.

Zakaj Novartis?
Naš namen je soustvarjati medicino za izboljšanje in podaljševanje življenja ljudi, naša vizija pa je postati najbolj cenjeno in zaupanja vredno farmacevtsko podjetje na svetu. Kako lahko to dosežemo? S pomočjo naših ljudi. Prav naši sodelavci nas vsak dan spodbujajo, da dosežemo svoje ambicije. Postanite del te misije in se nam pridružite! Več na spodnji povezavi: https://www.novartis.com/about/strategy/people-and-culture

Kaj nudimo:
Konkurenčen plačni paket, letni bonus, fleksibilen način dela, z možnostjo prilagajanja urnika in delom od doma, zaposlitev v podjetju s certifikatom TOP Employer, 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.

Pridružite se naši mreži Novartis: V kolikor se ne prepoznate v zgornjem opisu delovnega mesta, vas vabimo, da se vpišete na spodnji povezavi v Novartisovo bazo talentov saj lahko tako vašo vlogo upoštevamo za podobne pozicije v prihodnosti: https://talentnetwork.novartis.com/network

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

División
Operations
Business Unit
Innovative Medicines
Ubicación
Eslovenia
Sitio
Mengeš
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.

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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3. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Menge/QA-Compliance-Lead---Vodja-upravljanja-kakovosti---skladnost_REQ-10000613-1
4. mailto:diversity.inclusion_slo@novartis.com
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Menge/QA-Compliance-Lead---Vodja-upravljanja-kakovosti---skladnost_REQ-10000613-1