

Globalni vodja / analitske znanosti in tehnologije - aseptika, biološka zdravila, celice in geni (m/ž/d) / Global Head QC/AS&T Aseptics, Biologics, Cell and Gene (m/f/d)

Job ID
REQ-10044467

3月 24, 2025

Slovenia

摘要

#LI-Hybrid

Kot Globalni vodja / analitske znanosti in tehnologije - aseptika, biološka zdravila, celice in geni za procese kontrole kakovosti ter analitske znanosti in tehnologije boste opredelili, vodili in vzdrževali strategijo. V skladu s funkcijo globalnega nadzora kakovosti (QC) / analitskih znanosti in tehnologije (AS&T) bo ta vloga opredelila, vodila in vzdrževala strategijo in pobude za zagotavljanje doslednih in usklajenih standardov nadzora kakovosti v vseh laboratorijih in učinkovitosti laboratorijev, kar bo zagotovilo kompetentne in učinkovite organizacije za nadzor kakovosti v platformi / omrežju / na različnih platformah v eni od najbolj tehnološko napredna področja proizvodnje: biotehnologija.

We are seeking a Global Head QC/AS&T Aseptics, Biologics, Cell and Gene. In this role, you will define, drive and maintain both strategy and In alignment with the Global Quality Control (QC) /Analytical Sciences & Technology (AS&T) function, this role will define, drive and maintain both

strategy and initiatives to ensure consistent and harmonized Quality Control standards across all laboratories and laboratory efficiency, ensuring competent and efficient Quality Control organizations in a platform/network/across platforms in one of Novartis's most technologically advanced areas of manufacturing: Biotechnology.

About the Role

Vaš e ključne odgovornosti:

- Spodbuja izvajanje strategije nadzora kakovosti TechOps, da bi izkoristil skladnost in učinkovitost laboratorijev za nadzor kakovosti v organizaciji/lokacijah NTO v platformi in globalno standardizacijo/integracijo analitičnih poslovnih procesov in informacij, podatkov, globalnih standardov opreme in arhitekture aplikacij.
- Opredeljuje, načrtuje in vodi načrte kakovosti in tehnične programe, povezane z laboratoriji za nadzor kakovosti s poudarkom na splošnih ciljih, analitičnih prednostnih nalogah, novih tehnologijah/konceptih ali politikah/regulativnih zahtevah ter uveljavlja trenutne standarde, postopke in modul kakovosti ter direktive, globalne operativne postopke za analitične laboratorije, kot to zahtevajo cGMP. Ohranja ozaveščenost o regulativnih zahtevah, ki vplivajo na farmacevtsko industrijo.
- Sodeluje z vodjo kakovosti operativnih stroškov in vodjo analitične znanosti in tehnologije pri prepoznavanju in izvajanju pobud za skladnost in produktivnost v laboratorijih za analitiko (npr. vitki laboratorij, program za izboljšanje TMI).
- Odgovoren za poslovno načrtovanje, načrtovanje proračuna in virov za globalne projekte nadzora kakovosti ter mesečno spremljanje meritev globalnega nadzora kakovosti TechOps ter zagotavljanje, da so potrebni ukrepi sprejeti za doseganje ciljev in stopnjevanje z akcijskimi načrti na povezane deležnike.
- Zagotavlja tehnično strokovno znanje in smernice za namene regulativnih predložitvev in publikacij ter poročil o odzivih in špekcijskih pregledov.
- Spodbuja globalno standardizacijo/integracijo analitičnih poslovnih procesov in informacij, podatkov, globalnih standardov opreme in arhitekture aplikacij na celotni platformi, ocenjuje implementacijo novih tehnologij/sistemov/programske opreme.
- Opredeljuje in uveljavlja trenutne standarde, postopke ter module kakovosti in direktive, GOP za analitične laboratorije po potrebi. Ohranja ozaveščenost o regulativnih zahtevah, ki vplivajo na farmacevtsko industrijo.
- Zagotavljanje prispevkov k načrtom kapitalskih naložb za nadzor kakovosti / AST (analitične znanosti in tehnologija) za nadzor kakovosti, da se zagotovi preglednost načrtovane dokapitalizacije opreme, uvajanja novih tehnologij, novih IT aplikacij in potrebnih tehnologij.

Vaš doprinos k delovnem mestu:

- Izkušnje s sodelovanjem preko področij, medkulturne izkušnje, funkcionalna širina, vodenje ljudi in vodenje projektov.
- Obvladovanje tveganj, laboratorijska oprema, nadzor kakovosti (QC) in izkušnje s testiranjem.
- Izkušnje z upravljanjem proračunov in virov.
- Poznavanje vseh ustreznih politik, praks in zahtev glede skladnosti za vse notranje in zunanje predpise.

- Poznavanje TQM in sorodnih industrijskih standardov in procesov GxP.
- Aktivno pisno in govorno znanje angleškega jezika.

Z izbranim kandidatom bomo sklenili delovno razmerje za nedolga in uspešno dobo 6 mesecev. Prijavo oddajte z življenjepisom v slovenskem in angleškem jeziku.

Kaj nudimo:

Konkurenčni 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.

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Key Responsibilities:

- Drives TechOps Quality Control strategy implementation to leverage compliance & efficiency for Quality Control Labs across NTO organization/sites in a Platform and global standardization/integration of analytical business processes & information, data, global equipment standards & application architecture.
- Defines, plans & manages quality plans and technical programs related to Quality Control laboratories with emphasis on overall objectives, analytical priorities, new technology/concepts or policy/regulatory requirements and enforces current standards, procedures and Quality module and directives, Global Operating Procedures for Analytical Laboratories as required by cGMPs. Maintains awareness of regulatory requirements affecting the pharmaceutical industry.
- Collaborates with Head Quality OpEx and Head Analytical Sciences and Technology to identify and implement Compliance and Productivity initiatives across Analytics Labs (e.g Lean Lab, TMI Improvement Program).
- Responsible for business planning, budget and resource planning for the Global Quality Control Projects and follow-up on Global TechOps Quality Control metrics monthly and ensure that required actions taken to achieve the targets and escalate with the action plans to the related stakeholders.
- Provides technical expertise and direction for the purpose of regulatory submissions and publications as well as Inspection responses reports.
- Drives global standardization/integration of analytical business processes and information, data, global equipment standards and application architecture across the platform, evaluating the implementation of new technologies/systems/software.
- Defines & enforces current standards, procedures and Quality modules and directives, GOP for Analytical Laboratories as required. Maintains awareness of regulatory requirements affecting the pharmaceutical industry.

- Provide input to the site 's Quality Control/AST (Analytical Sciences & Technology) Quality Control capital investment plans to provide transparency of scheduled equipment recapitalization, new technology introduction, new IT applications & technologies needed.

Essential Requirements:

- Experience in collaborating across boundaries, Cross Cultural Experience, Functional Breadth, People Leadership and Project Management.
- Risk Management, laboratory equipment, Quality Control (QC) and testing experience.
- Experience managing budgets and resources.
- Knowledge of all relevant policies, practices, and compliance requirement for all internal and external regulations.
- Knowledge of TQM and related industry GxP standards and processes.
- Fluent in English, 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>

部门

Operations

Business Unit

Innovative Medicines

地点

Slovenia

站点

Ljubljana

Company / Legal Entity

SI19 (FCRS = SI019) Novartis farmacevtska proizvodnja d.o.o.

Alternative Location 1

Barcelona Gran V í a, Spain

Alternative Location 2

Schaftenau, Austria

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.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.

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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