

Specialist upravljanja kakovosti za področje skladnosti računalniških sistemov / QA eCompliance Specialist

Job ID
REQ-10053523

May 28, 2025

Slovenia

Summary

#LI-Hybrid

Location: Ljubljana, Slovenia

Vas zanima upravljanje kakovosti v farmacevtski industriji v povezavi s skladnostjo računalniških sistemov? Ste proaktivna in visoko motivirana oseba, ki si želite izvesti in tesnega timskega dela na globalnem nivoju? Imate izobrazbo farmacevtske ali druge primerljive smeri z želijo za računalništvo? Vas je vedno zanimalo kako izgledajo procesi v farmacevtski industriji? Ste natančna, zanesljiva in komunikativna oseba, ki si prizadeva za stalno profesionalno rast in iščete priložnosti za napredovanje na naslednjo stopnjo v svoji karieri?

e se najdete v katerem od zgornjih opisov vas vabimo, da se pridružite ekipi QA eCompliance na Novartisovi lokaciji v Ljubljani!

Are you interested in quality management in the pharmaceutical industry in connection with computer system compliance? Are you a proactive and highly motivated person who seeks challenges and close teamwork at a global level? Do you have an education in pharmacy or a similar field with an affinity for IT? Have you always been interested in how processes work in the pharmaceutical industry? Are you a precise, reliable, and communicative person who strives for continuous professional growth and seeks opportunities for advancement to the next level in your career?

If you identify with any of the above descriptions, we invite you to join the QA eCompliance team at Novartis' location in Ljubljana!

About the Role

Vaše ključne odgovornosti:

- Nudjenje podpore pri dejavnostih za kvalifikacijo in validacijo raznih sistemov (nastavitev, svetovanje, pregled).
- Zagotavljanje implementacije veljavnih Novartisovih in regulatornih zahtev za podprtje GxP raznih sistemov.
- Pregled / odobritev nadziranja sprememb v sistemu.
- Zagotavljanje kakovosti procesa v skladu s predpisi.
- Zagotavljanje strokovnega znanja oz. usmeritev za zagotavljanje kakovosti in ustreznosti GxP relevantnih raznih sistemov, ocenjevanje dobaviteljev, nadzor nad spremembami, obvladovanje odstopov in povezanih aktivnosti, sicer se zagotovi skladnost z regulatornimi predpisi in uresničijo pri akovanju podjetja.
- Pregledovanje in potrjevanje ocen opreme/sistemov glede GxP relevantnosti.
- Implementiranje in razvijanje novih zmogljivosti v skladu s poslovnimi potrebami.
- Priprava in podpora pri revizijah in špekcijskih pregledih.

Vaše doprinos k delovnemu mestu:

- Visokošolska/univerzitetna izobrazba farmacevtske, kemijske, raznih in drugih naravoslovne in tehnične smeri.
- Aktivno znanje angleškega jezika.
- Poznavanje orodja Microsoft Office.
- Minimalno 3 let delovnih izkušenj s podprtjo avtomatizacije/CSV ali minimalno 3 leta delovnih izkušenj iz laboratorijskih praks in / ali avtomatizacije procesov in sistemov ter standardov s podprtjo raznih sistemov v farmacevtski industriji ali drugi ustreznosti industriji.

Z izbranim kandidatom bomo sklenili delovno razmerje za določen razpon do 6 mesecev.

Kaj nudimo:

Konkurenčni 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 dogodki in neomejene priložnosti za učenje in razvoj.

Predani smo raznolikosti in vključenosti

Novartis si prizadeva ustvariti izjemno, vključno in delovno okolje in oblikovanje raznolikih timov, saj ti predstavljajo naše bolnike in skupnosti, ki jih oskrbujemo.

Dostop in prilagoditve

V Novartisu si prizadevamo k vključenosti oseb z invalidnostjo in zagotavljanju ustreznih prilagoditev delovnega okolja posameznikom z omejitvami. V kolikor zaradi bolezni ali invalidnosti potrebujete ustreerne prilagoditve v kateremkoli delu selekcijskega procesa ozziroma potrebujete prilagoditve pri izvajanju osnovnih nalog na delovnem mestu, nam pišite na naslov diversity.inclusionslo@novartis.com in navedite, kakšne prilagoditve potrebujete ter vaše kontaktne podatke. Prosimo, vključite tudi podatek o številki razpisa, na katerega se prijavljate.

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Key Responsibilities:

- Support site qualification and validation activities (planning, advising, review).
- Audit and inspection preparation and support.
- Change control review/approval.
- Ensure process quality assurance acc. to regulations.
- Ensure implementation of the applicable Novartis and regulatory requirements for GxP regulated computerized systems.
- Provide quality assurance expertise / guidance for GxP computerized systems classification, qualification, supplier assessment, change control, deviation management and associated activities that ensure compliance to regulatory and company expectations.
- Review and approve determination of computerized system for GxP applicability.
- Adopts & develops new capabilities in alignment with Business needs.

Essential Requirements:

- Degree in chemistry, biology, computer science, life sciences.
- Functional knowledge of English.
- Knowledge of Microsoft Office.
- Minimum 3 years of overall automation/CSV experience, or a minimum of 3 years of Laboratory.

We offer temporary employment with 6 months of probation period.

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), 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.

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.

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>

部門
Operations

部門
Innovative Medicines

国
Slovenia

勤務地
Ljubljana

Company / Legal Entity
SI19 (FCRS = SI019) Novartis farmacevtska proizvodnja d.o.o.

Alternative Location 1
Menge š , Slovenia

Functional Area
Quality

職種
Full time

雇用形態
Temporary (Fixed Term)

Shift Work
No

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