Specialist upravljanja kakovosti za podro č je skladnosti ra č unalni š kih sistemov (m/ ž /d) / QA eCompliance Specialist (m/f/d)

Job ID
REQ-10025511

1月 10, 2025

Slovenia

摘要

Kot Specialist upravljanja kakovosti za podro č je skladnosti ra č unalni š kih sistemov boste odgovorni za skladnost in podporo pri zagotavljanju sistema kakovosti za podro č je GxP relevantnih ra č unalni š ko podprtih sistemov, vklju č no z oceno/upravljanjem kakovosti dobaviteljev za celotni ž ivljenjski cikel v skladu z veljavnimi predpisi, internimi predpisi, ki so opredeljeni v Novartisovem priro č niku in postopkih za kakovost, dobrimi praksami in poslovnimi cilji. Skladnost ra č unalni š kih sistemov nudi usmeritve za podro č ja in informacije povezane z validacijami ra č unalni š kih sistemov (CSV). Odgovornost za pregled in/ali odobritev kvalifikacij in rezultatov operativnih nalog oz. dejavnosti ra č unalni š ko podprtih sistemov v skladu z GxP. Delovanje skladno z zakonodajo, internimi predpisi, dobrimi praksami in poslovnimi cilji.

We are seeking a QA eCompliance Specialist. In this role, you will be responsible for the compliance and Quality Assurance support of the GxP computerized systems including supplier quality assessment/management throughout their lifecycles in regards to the applicable regulations and requirements defined in the Novartis Quality Manual and procedures. eCompliance provides

guidance on Computer System Validation (CSV) related topics and related information. Reviews and/or approves the qualification and operational deliverables of respective GxP computerized systems. Managing work in accordance with the law, internal regulations, good practices and business objectives.

About the Role

Va š e klju č ne odgovornosti:

- Nudenje podpore pri dejavnostih za kvalifikacijo in validacijo (na č rtovanje, svetovanje, pregled).
- Priprava in podpora pri revizijah in in š pekcijskih pregledih.
- Pregled / odobritev nadziranja sprememb.
- Zagotavljanje kakovosti procesa v skladu s predpisi.
- Zagotavljanje implementacije veljavnih Novartisovih in regulatornih zahtev za podro č je GxP ra č unalni š ko podprtih sistemov.
- Zagotavljanje strokovnega znanja oz. usmeritev za zagotavljanje kakovosti in ustreznosti GxP relevantnih ra č unalni š ko podprtih sistemov, ocenjevanje dobaviteljev, nadzor nad spremembami, obvladovanje odstopov in povezanih aktivnosti, s č imer se zagotovi skladnost z regulatornimi predpisi in uresni č ijo pri č akovanja podjetja.
- Pregledovanje in potrjevanje ocen opreme/sistemov glede GxP relevantnosti.
- Implementiranje in razvijanje novih zmogljivosti v skladu s poslovnimi potrebami.

Va š doprinos k delovnem mestu:

- Visoko š olska/univerzitetna izobrazba farmacevtske, kemijske, ra č unalni š ke ali druge naravoslovne in tehni č ne smeri.
- Aktivno znanje angle š kega jezika.
- Poznavanje orodja Microsoft Office.
- Minimalno 3 let delovnih izku š enj s podro č ja avtomatizacije/CSV ali minimalno 3 leta delovnih izku š enj iz laboratorijskih praks in / ali avtomatizacije procesov in sistemov ter standardov s podro č ja ra č unalni š kih sistemov v farmacevtski industriji ali drugi ustrezni industriji.

Z izbranim kandidatom bomo sklenili delovno razmerje za **dolo č en č as** s poskusno dobo **6 mesecev.**

Kaj nudimo:

Konkuren č en pla č ni paket, letni bonus, fleksibilen na č in dela, z mo ž nostjo prilagajanja urnika in delom od doma, pokojninsko shemo, shemo nagrajevanja in priznanja dose ž kov, raz š irjeni program promocije zdravja na podro č ju telesnega, du š evnega in dru ž benega po č utja (Polni ž ivljenja) ter dogodke, neomejene prilo ž nosti za u č enje in razvoj.

Predani smo raznolikosti in vklju č **enosti**

Novartis si prizadeva ustvariti izjemno, vklju č ujo č e delovno okolje in oblikovanje raznolikih timov, saj ti predstavljajo na š e bolnike in skupnosti, ki jih oskrbujemo.

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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.

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.

Functional Area
Quality

Job Type
Full time

Employment Type
Temporary (Fixed Term)

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.

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