Specialist upravljanja kakovosti za področje skladnosti računalniških sistemov (m/ž/d) / QA eCompliance Specialist (m/f/d)

Job ID
REQ-10025511
Ene 10, 2025
Eslovenia

Resumen

Kot Specialist upravljanja kakovosti za področje skladnosti računalniških sistemov boste odgovorni za skladnost in podporo pri zagotavljanju sistema kakovosti za področje GxP relevantnih računalniško podprtih sistemov, vključno z oceno/upravljanjem kakovosti dobaviteljev za celotni življenjski cikel v skladu z veljavnimi predpisi, internimi predpisi, ki so opredeljeni v Novartisovem priročniku in postopkih za kakovost, dobrimi praksami in poslovnimi cilji. Skladnost računalniških sistemov nudi usmeritve za področja in informacije povezane z validacijami računalniških sistemov (CSV). Odgovornost za pregled in/ali odobritev kvalifikacij in rezultatov operativnih nalog oz. dejavnosti računalniško 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

Vaše ključne odgovornosti:

- Nudenje podpore pri dejavnostih za kvalifikacijo in validacijo (načrtovanje, svetovanje, pregled).
- Priprava in podpora pri revizijah in inšpekcijskih pregledih.
- Pregled / odobritev nadziranja sprememb.
- Zagotavljanje kakovosti procesa v skladu s predpisi.
- Zagotavljanje implementacije veljavnih Novartisovih in regulatornih zahtev za področje GxP računalniško podprtih sistemov.
- Zagotavljanje strokovnega znanja oz. usmeritev za zagotavljanje kakovosti in ustreznosti GxP relevantnih računalniško podprtih sistemov, ocenjevanje dobaviteljev, nadzor nad spremembami, obvladovanje odstopov in povezanih aktivnosti, s čimer se zagotovi skladnost z regulatornimi predpisi in uresničijo pričakovanja podjetja.

- Pregledovanje in potrjevanje ocen opreme/sistemov glede GxP relevantnosti.
- Implementiranje in razvijanje novih zmogljivosti v skladu s poslovnimi potrebami.

Vaš doprinos k delovnem mestu:

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

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

Kaj nudimo:

Konkurenčen 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:

- 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

División
Operations
Business Unit
Innovative Medicines
Ubicación
Eslovenia
Sitio
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.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.

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representative of the patients and communities we serve.

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