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

Job ID
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Résumé

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

Če 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? Are you coming from engineering, mechatronics, or computer science, and 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:

- Nudenje podpore pri dejavnostih za kvalifikacijo in validacijo računalniško podprtih sistemov (načrtovanje, svetovanje, pregled).
- Zagotavljanje implementacije veljavnih Novartisovih in regulatornih zahtev za področje GxP računalniško podprtih 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 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.
- Priprava in podpora pri revizijah in inšpekcijskih pregledih.

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

Division
Operations
Business Unit
Innovative Medicines
Emplacement
République de Slovénie
Site
Ljubljana
Company / Legal Entity
SI19 (FCRS = SI019) Novartis farmacevtska proizvodnja d.o.o.
Functional Area
Qualité
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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