NOVARTIS

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

Job ID
REQ-10071882
Mar 12, 2026
LOC_SI

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 tehnične, računalniške ali druge naravoslovne smeri.
- Aktivno znanje angleškega jezika.
- Poznavanje orodja Microsoft Office.
- Minimalno 3 let delovnih izkušenj s področja avtomatizacije/CSV 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, zaposlitev v podjetju s certifikatom TOP Employer, pokojninsko shemo, shemo nagrajevanja in priznanja dosežkov, razširjeni program promocije zdravja na področju telesnega, duševnega indružbenega počutja (Polni življenja) ter dogodki in 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.

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 ustrezne prilagoditve v kateremkoli delu selekcijskega procesa oziroma potrebujete prilagoditve pri izvajanju osnovnih nalog na delovnem mestu, nam pišite na

naslov diversity.inclusion_slo@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:

- University-level education in a technical, computer science, or other natural science field.
- Active knowledge of the English language.
- Familiarity with Microsoft Office tools.
- At least 3 years of work experience in the field of automation/CSV and/or process and system automation, as well as standards related to computer systems in the pharmaceutical industry or another relevant industry.
- 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.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.

Role Requirements

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

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

Division
DIV_TO
Business Unit

Quality
Location
LOC_SI
Site
Ljubljana
Company / Legal Entity
SI19 (FCRS = SI019) Novartis farmacevtska proizvodnja d.o.o.
Functional Area
FCT_QA
Job Type
Full time
Employment Type
Začasni sodelavec (za določen čas)
Shift Work
No
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2. mailto:diversity.inclusion_slo@novartis.com
3. mailto:diversity.inclusion_slo@novartis.com
4. https://www.novartis.com/about/strategy/people-and-culture
5. https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf
6. https://novartis.wd3.myworkdayjobs.com/sl-SI/Novartis_Careers/job/Ljubljana/Specialist-upravljanja-kakovosti-za-podroje-skladnosti-raunalnikih-sistemov---QA-eCompliance-Specialist--m-f-d-_REQ-10071882
7. https://novartis.wd3.myworkdayjobs.com/sl-SI/Novartis_Careers/job/Ljubljana/Specialist-upravljanja-kakovosti-za-podroje-skladnosti-raunalnikih-sistemov---QA-eCompliance-Specialist--m-f-d-_REQ-10071882