Validation Lead (m/f/d)/Vodja validacij (m/ ž /d)

Job ID
REQ-10057652

7月 18, 2025

Slovenia

摘要

#LI-Hybrid
Location: Ljubljana, Slovenija

Postani klju č na oseba pri zagotavljanju robustnih procesov, v stalnem stanju validiranosti in neprestanih izbolj š av zmogljivosti procesov, vrednotenih s pomo č jo statisti č nih analiz kriti č nih parametrov v MS&T kot Vodja validacij (m/ ž /d). V tej vlogi bo š vodila razvoj in izvajanje validacijskih strategij, ki so temelj za varno, u č inkovito in skladno delovanje proizvodnih procesov. Prevzela bo š odgovornost za razvoj, implementacijo in opravljanje procesnih validacij, validacij pakiranja, validacij č i š č enja in revalidacij, skladno s č asovnimi roki ter razpolo ž ljivimi sredstvi. Pri tem bo š zagotavljala skladnost z veljavno zakonodajo, dobrimi praksami, internimi predpisi, standardi kakovosti in zahtevami agencij za zdravila. Č e te navdu š uje delo v reguliranem okolju, kjer lahko s svojim strokovnim znanjem resni č no vpliva š - potem je to prilo ž nost zate.

Become a key figure in ensuring robust processes, maintaining a constant state of validation, and continuously improving process performance, evaluated through statistical analysis of critical parameters in MS&T, as a Validation Lead (m/f/d). In this role, you will lead the development and implementation of validation strategies that form the foundation for safe, effective, and compliant manufacturing operations. You will take responsibility for the development, implementation, and execution of process validations, packaging validations, cleaning validations, and revalidations, in line with timelines and available resources. In doing so, you will ensure compliance with applicable legislation, good practices, internal regulations, quality standards, and regulatory agency requirements. If you are passionate about working in a regulated environment where your expertise can truly make an impact - then this is the opportunity for you.

About the Role

Va š **e klju** č **ne odgovornosti:**

- Razvijaj in izvajaj strategije validacije procesov, č i š č enja, pakiranja in teko č ega preverjanja.

- Zagotavljaj skladnost validacij z GMP, internimi predpisi, zakonodajo in standardi kakovosti.

- Vzpostavljaj in vzdr ž uj glavni na č rt validacije ter spremljaj validacijski status lokacije.

- Pripravljaj validacijske protokole in dokumentacijo ter vodi validacijske aktivnosti.

- Svetuj pri ocenjevanju tveganj in izvajanju validacijskih strategij za nove izdelke.

- Sodeluj pri prenosih in lansiranjih izdelkov ter pripravi registracijske dokumentacije.

- Koordiniraj z oddelki za in ž eniring, IT, QC in AS&T pri kvalifikacijah in validacijah.

- Gostuj validacijske seje in zastopaj lokacijo v validacijski mre ž i.

- Skrbi za usposabljanje in razvoj sodelavcev ter upravljaj u č ne na č rte.

- Podpiraj izvajanje Novartisovih proizvodnih praks in zagotavljaj trajnostno poslovanje.

Va š **doprinos k delovnem mestu:**

- Zaklju č ena visoko š olska izobrazba naravoslovne, farmacevtske ali tehni č ne smeri.

- Izku š nje z validacijo procesov, č i š č enja in pakiranja v reguliranem okolju.

- Dobro poznavanje zahtev dobre proizvodne prakse (GMP) in zakonodaje s podro č ja zdravil.

- Sposobnost priprave validacijske dokumentacije in vodenja validacijskih aktivnosti.

- Izku š nje s sodelovanjem z razli č nimi oddelki (npr. IT, QC, in ž eniring) pri validacijah.

- Sposobnost ocenjevanja tveganj in uporabe orodij za upravljanje tveganj.

- Aktivno znanje angle š kega jezika v pisni in ustni obliki.

Za ž **eleno:**

- Aktivno znanje slovenskega jezika.

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

Zakaj Novartis?

Na š namen je soustvarjati medicino za izbolj š anje in podalj š evanje ž ivljenja ljudi, na š a vizija pa je postati najbolj cenjeno in zaupanja vredno farmacevtsko podjetje na svetu. Kako lahko to dose ž emo? S pomo č jo na š ih ljudi. Prav na š i sodelavci nas vsak dan spodbujajo, da dose ž emo svoje ambicije. Postanite del te misije in se nam pridru ž ite! Ve č na spodnji povezavi:
https://www.novartis.com/about/strategy/people-and-culture

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, zaposlitev v podjetju s certifikatom TOP Employer, 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.

Pridru ž **ite se na** š **i mre** ž **i Novartis:**

V kolikor se ne prepoznate v zgornjem opisu delovnega mesta, vas vabimo, da se vpi š ete na spodnji

povezavi v Novartisovo bazo talentov saj lahko tako va š o vlogo upo š tevamo za podobne pozicije v prihodnosti: https://talentnetwork.novartis.com/network

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Key Responsibilities:

- Develop and execute validation strategies for processes, cleaning, packaging, and ongoing process verification.

- Ensure validation compliance with GMP, internal policies, legislation, and quality standards.

- Establish and maintain the site validation master plan and monitor validation status.

- Prepare validation protocols and documentation and lead validation activities.

- Advise on risk assessments and validation strategies for new product introductions.

- Participate in product transfers and launches and support registration documentation preparation.

- Coordinate with Engineering, IT, QC, and AS&T departments on qualifications and validations.

- Host validation board meetings and represent the site in the validation network.

- Support training and development of team members and manage training curricula.

- Support implementation of Novartis manufacturing practices and ensure business continuity.

What you will bring to the role:

- University degree in natural sciences, pharmacy, or technical field.

- Experience in process, cleaning, and packaging validation in a regulated environment.

- Strong knowledge of GMP requirements and pharmaceutical legislation.

- Ability to prepare validation documentation and lead validation activities.

- Experience collaborating with departments such as IT, QC, and Engineering.

- Risk assessment skills and familiarity with risk management tools.

- Fluent in English, both written and spoken.

Desirable Requirements:

- Fluent in Slovenian language.

We offer **permanent employment** with **6 months** of probation period.

Why Novartis?

Our purpose is to reimagine medicine to improve and extend people ' s lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

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, 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.

Join our Novartis Network:
If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network

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
Technical Operations

Job Type
Full time

Employment Type
Regular

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.

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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