NOVARTIS

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

Job ID
REQ-10078184
Июн. 22, 2026
Словения
Available in: English

Сводка

#LI-Hybrid
Location: Ljubljana, Slovenija
Relocation Support: This role is based in Ljubljana Slovenia. Novartis is unable to offer relocation support: please only apply if accessible.

Pridružite se nam kot Vodja validacij (m/ž/d) in sodelujte pri zagotavljanju procesov v stalnem stanju validiranosti ter pri neprestanih izboljšavah zmogljivosti procesov, vrednotenih s pomočjo statističnih analiz kritičnih parametrov v MS&T. V tej vlogi boste vodili razvoj in izvajanje validacijskih strategij, ki so temelj za varno, učinkovito in skladno delovanje proizvodnih procesov. Prevzeli boste odgovornost za razvoj, implementacijo in opravljanje procesnih validacij, validacij pakiranja, validacij čiščenja in revalidacij, skladno s časovnimi roki ter razpoložljivimi sredstvi. Pri tem boste zagotavljali skladnost z veljavno zakonodajo, dobrimi praksami, internimi predpisi, standardi kakovosti in zahtevami agencij za zdravila.

Če vas navdušuje delo v reguliranem okolju, kjer lahko s svojim strokovnim znanjem resnično vplivate – potem je to priložnost za vas.

About the Role

Vaše ključne odgovornosti:

- Razvijanje in izvajanje strategije validacije procesov, čiščenja, pakiranja in tekočega preverjanja.
- Zagotavljanje skladnosti validacij z GMP, internimi predpisi, zakonodajo in standardi kakovosti.
- Vzpostavljanje in vzdrževanje glavnih načrtov validacije ter spremljanje validacijskih statusov lokacije.
- Pripravljanje validacijskih protokolov in dokumentacije ter vodenje validacijskih aktivnosti.
- Svetovanje pri ocenjevanju tveganj in izvajanju validacijskih strategij za nove izdelke.
- Sodelovanje pri prenosih in lansiranjih izdelkov ter pripravi registracijske dokumentacije.
- Koordiniranje z oddelki za inženiring, IT, QC in AS&T pri kvalifikacijah in validacijah.
- Vodenje validacijskih sej in zastopanje lokacije v validacijski mreži.
- Skrb za usposabljanje in razvoj sodelavcev ter upravljanje učnih načrtov.
- Podpiranje pri izvajanju Novartisovih proizvodnih praks in zagotavljanje trajnostnega poslovanja.

Vaš doprinos k delovnem mestu:

- Zaključena visokošolska izobrazba naravoslovne, farmacevtske ali tehnične smeri.
- Izkušnje z validacijo procesov, čiščenja in pakiranja v reguliranem okolju (zaželeno vsaj 5 let izkušenj).
- Dobro poznavanje zahtev dobre proizvodne prakse (GMP) in zakonodaje s področja zdravil.
- Sposobnost priprave validacijske dokumentacije in vodenja validacijskih aktivnosti.
- Izkušnje s sodelovanjem z različnimi oddelki (npr. IT, QC, inženiring) pri validacijah.
- Sposobnost ocenjevanja tveganj in uporabe orodij za upravljanje tveganj.
- Aktivno znanje angleškega jezika v pisni in ustni obliki, poznavanje lokalnega jezika (slovenščina) je prednost.

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

Ugodnosti in nagrajevanje:

Konkurenčen plačni paket, letni bonus, fleksibilen način dela z možnostjo prilagajanja urnika in delom od doma, pokojninska shema, shema nagrajevanja in priznanja dosežkov, razširjeni program promocije zdravja na področju telesnega, duševnega in fizičnega počutja (iniciativa Polni življenja), številne priložnosti za učenje in razvoj.

Preberite naš priročnik, da spoznate načine, s katerimi bomo spodbujali vaš osebni in profesionalni razvoj:https://www.novartis.com/careers/benefits-rewards

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.

Pridružite se Novartisu: Ni pravo delovno mesto za vas? Prijavite se v našo bazo talentov, da ostanete v kontaktu z nami in se seznanite z ustreznimi kariernimi priložnostmi takoj, ko se pojavijo: https://talentnetwork.novartis.com/network

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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.

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. Fluent in Slovenian language is an advantage.

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

Benefits and Rewards:

Competitive salary, Annual bonus, Flexible working schedule, tailored to your needs, possibility to work from home, Pension scheme, possibility of joining collective health insurance scheme, Employee Recognition Scheme, Expanded program for the promotion of health in the field of physical and mental well-being and managing workload (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

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

Primary location salary range
$0.00 - $0.00
Дивизион
Operations
Business Unit
Production / Manufacturing
Место
Словения
Сайт
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

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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