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

Job ID
385758BR
Mai 10, 2024
Slowenien

Zusammenfassung

Kot Vodja validacij (m/ž/d) boste odgovorni za pripravo, vodenje in izvedbo procesnih validacij v proizvodnji bioloških učinkovin in izdelkov, validacije čiščenja in drugih procesov v predvidenih rokih ter z razpoložljivimi sredstvi, skladno s trenutno veljavnimi standardi, zakonodajo, internimi predpisi, dobrimi praksami in poslovnimi cilji. Imeli boste ključno vlogo pri zagotavljanju validiranosti proizvodnih procesov in s tem zagotavljanju dosledne proizvodnje zdravil najvišje kakovosti. Z ekipo strokovnjakov z različnih funkcij znotraj enote in v globalnem okolju boste razvijali robustne validacijske strategije, ki izpolnjujejo specifične zahteve izdelkov, kakovosti ter cGMP. Imeli boste priložnost nadgraditi svoje znanje in izkušnje na vznemirljivem področju biofarmacevtskih izdelkov. _____ As a Validation Lead (m/f/d) you will be responsible for preparing, managing and executing process validations in the production of biological drug substances and products, validation of cleaning and other processes on time and with available resources, in accordance with cGMP, internal standards, and business goals. You will play a key role enabling that our manufacturing processes consistently produce medicines at the highest quality. You will collaborate in cross-functional teams to develop robust validation strategies meeting product specific requirements and cGMP standards and quality expectations. You will have the opportunity to increase your knowledge and expertise in the exciting field of biopharmaceuticals.

About the Role

Lokacija: Slovenija, Poljska, Turčija #LI-Hybrid

Iščemo visoko motiviranega sodelavca, ki se bo pridružil naši MS&T ekipi pri širjenju proizvodnih zmogljivosti za proizvodnjo bioloških zdravil. Edinstven pristop k “single-use” tehnologiji nam omogoča proizvodnjo visokokakovostnih bioloških zdravil z neprimerljivo učinkovitostjo. Z našo najsodobnejšo tehnologijo in procesi, širokim naborom bioloških zdravil ter našim znanjem, predanostjo in vrhunskimi ekipami sodelavcev smo tovarna prihodnosti in z veseljem pozdravljamo talentiranega posameznika v naši ekipi.

Vaše ključne odgovornosti:
• Odgovornost za vzpostavitev, izvajanje in sledenje glavnega validacijskega načrta za validacijo procesov (vključno s procesom čiščenja) ter tekoče preverjanje procesov (OPV).
• Opredeljuje in izvaja validacijsko strategijo (za proces, čiščenje, tekoče preverjanje) in jo zagovarja pred inšpekcijskimi organi.
• Skrbi za to, da so vsi proizvodni in čistilni procesi validirani, vodi pregled validacijskega statusa, spremlja ključne kazalnike uspešnosti ter ohranja validacijske aktivnosti v stanju pripravljenosti na inšpekcijske preglede.
• Izdeluje in pregleduje ocene tveganja za validacijo in tekoče preverjanje procesov, pripravlja zahtevnejše validacijske protokole in validacijska poročila, vzpostavlja lokalne postopke in predloge za ustrezno

validacijsko dokumentacijo.
• S tehničnim razvojem, skrbnikom izdelkov, proizvodnjo, enoto za kontrolo in zagotavljanje kakovosti ter drugimi funkcijami sodeluje pri prenosih in lansiranjih izdelkov, kjer prispeva tehnično strokovno znanje in sooblikuje strategijo validacije.
• Sodeluje pri pripravi registracijske dokumentacije vezano na validacije procesov.

Vaš doprinos k delovnem mestu:
• Univerzitetna stopnja izobrazbe iz farmacije, farmacevtske tehnologije, biotehnologije, kemije, inženirskih znanosti ali druge ustrezne znanstvene smeri. Zaželen magisterij ali doktorat.
• Vsaj 5 let delovnih izkušenj iz farmacevtske proizvodnje, proizvodnje bioloških učinkovin, ali 8 let primerljivih izkušenj (npr. živilska, druga GMP regulirana proizvodnja).
• Aktivno znanje angleškega jezika.
• Poznavanje sistemov kakovosti in regulatornih zahtev.
• Dokazano obvladovanje pisanja in pregledovanje tehnične dokumentacije.
• Dobre komunikacijske sposobnosti, proaktivnost, samoiniciativnost, strokovnost, ciljna naravnanost.

Zaželene izkušnje:
• Izkušnje iz projektnega vodenja v več-funkcijskem okolju.
• Uporaba statističnih orodij.
• Dobro upravljanje z različnimi deležniki.
• Zmožnost delovanja v globalnem okolju.

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

Zakaj Novartis?

Naš namen je soustvarjati medicino za izboljšanje in podaljševanje življenja ljudi, naša vizija pa je postati najbolj cenjeno in zaupanja vredno farmacevtsko podjetje na svetu. Kako lahko to dosežemo? S pomočjo naših ljudi. Prav naši sodelavci nas vsak dan spodbujajo, da dosežemo svoje ambicije. Postanite del te misije in se nam pridružite! Več na spodnji povezavi: https://www.novartis.com/about/strategy/people-and-culture

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 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.

Pridružite se naši mreži Novartis: V kolikor se ne prepoznate v zgornjem opisu delovnega mesta, vas vabimo, da se vpišete na spodnji povezavi v Novartisovo bazo talentov saj lahko tako vašo vlogo upoštevamo za podobne pozicije v prihodnosti: https://talentnetwork.novartis.com/network

Location: Slovenia, Poland, Turkey #LI-Hybrid

We are seeking a highly motivated Validation Lead to join MS&T team as we expand our manufacturing capabilities for the production of biologics. Our outstanding approach to single-use technology allows us to produce high-quality biological drugs substances with unparalleled efficiency. Our state-of-the-art technology and processes, a wide range of biological molecules, engaged and highly motivated teams committed to improve people's lives make us a factory of the future, and we are eager to welcome a dedicated individual to our team.

Key Responsibilities:

• Responsible for establishing, implementing and monitoring the validation master plan for process validation (including the cleaning process) and ongoing process verification (OPV).
• Defines and implements a validation strategy (for process, cleaning, OPV) and defends it to authorities.
• Ensures that production and cleaning processes are validated, overviews the validation status, supervises key performance indicators and maintains validation activities in a state of readiness for inspections.
• Conducts and reviews risk assessments for validation and ongoing process verification, prepares complex validation protocols and validation reports, establishes local procedures and templates of validation documentation.
• Participates in process transfers and launches. Together with technical development, manufacturing, quality unit and other functions provides technical expertise and co-develops the validation strategy for the product.
• Participates in the preparation of registration dossiers related to process validation.

Essential Requirements:

• BSc. in Chemistry, Pharmacy, Biotechnology, Pharmaceutical Technology or equivalent. Desirable MSc / PhD in the above.
• Minimum 5 years experience in pharmaceutical manufacturing, GMP manufacturing, technical development or quality or 8 years in comparable highly regulated industry.
• Functional knowledge of English.
• Proven understanding of quality systems and regulatory requirements across multiple health authorities.
• Expert in reviewing and writing technical reports.
• Good communication skills, proactive behaviour.

Desirable Requirements:

• Proven project management experience in a cross-functional environment.
• Knowledge of statistical tools.
• Good management with different stakeholders.
• Ability to operate in a global environment.

We offer a **temporary 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 (Well-being), employment at Top SI Employer, 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

Abteilung
Operations
Business Unit
Innovative Medicines
Ort
Slowenien
Website
Mengeš
Company / Legal Entity
SI19 (FCRS = SI019) Novartis farmacevtska proizvodnja d.o.o.
Alternative Location 1
Türkei
Alternative Location 2
Polen
Functional Area
Technical Operations
Job Type
Full time
Employment Type
Temporary (Fixed Term)
Shift Work
No
Apply to Job

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.

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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