Ekspert validacij (m/ž/d) / Validation Expert (m/f/d)

Job ID
REQ-10030101
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Résumé

#LI-Hybrid

Kot Ekspert validacij boste odgovorni za izvajanje in upravljanje validacij procesov, validacij čiščenja in sprememb, ki zagotavljajo skladnost s trenutno veljavnim GMP, standardi kakovosti in globalnimi zahtevami za validacije, skladno z zakonodajo, internimi predpisi, dobrimi praksami in poslovnimi cilji.

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As a Validation Expert you will be responsible for executing and managing process and cleaning validation activities and change management activities to meet cGMP requirements on time and quality to ensure that site validation programs are compliant with global regulatory expections, in accordance with legislation, internal rules, good practices and business objectives.

About the Role

Vaše ključne odgovornosti:

- Skrbnika izdelkov podpira pri vzdrževanju strategije kontrole procesov. Parametre veljavnih procesov in strategijo kontrole procesov pretvarja v jasen načrt validacije procesov.
- Zagotavlja tehnično strokovno znanje in po potrebi skrbi za lažjo pripravo ocene tveganja glede kakovosti.
- Podporo aktivnostim za upravljanje življenjskega cikla validacije procesov nudi z vzdrževanjem statusa kontrole s tekočim preverjanjem procesov. Skrbi za to, da se opredelijo ustrezne spremenljivke za tekoče spremljanje, ki prispevajo k aktivnostim za upravljanje tveganj na področju kakovosti.
- Pripravlja in pregleduje protokole in poročila za validacijo procesov, pakiranja ali čiščenja, protokolov in poročil za tekoče preverjanje procesov in čiščenja.
- Podpira izvajanje validacijskih aktivnosti v proizvodnih prostorih.
- Vse aktivnosti in projekte, za katere je odgovoren, ohranja v statusu pripravljenosti na inšpekcijske preglede.
- Skrbi za to, da se izvedejo vse validacijske aktivnosti na lokaciji in da so v skladu s trenutnimi zahtevami Novartisa in cGMP, upravlja odstopanja v zvezi z validacijo procesov in daje predloge za njihovo reševanje in preprečevanje ponovitve.
- S sodelovanjem pri pripravi na validacijo in ocenjevanju tveganj zagotavlja uspešnost validacije procesa komercializacije.
- Druge naloge po navodilu nadrejenega in naloge na podlagi posebnega imenovanja.

Vaš doprinos k delovnem mestu:

- Univerzitetna diploma kemijske ali farmacevtske smeri, kemijskega inženiringa ali farmacevtske tehnologije.
- Minimalno 3 leta izkušenj na področju proizvodnje / proizvodne znanosti in tehnologije / tehničnega razvoja / kakovosti.
- Aktivno znanje angleškega jezika.
- Poznavanje orodja Microsoft Office.

Z izbranim kandidatom bomo sklenili delovno razmerje za **določen čas enega leta** 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 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 Product Steward in maintaining the process control strategy. Translate applicable process parameters and the process control strategy into a focused validation plan for process validation.
- Provide technical expertise and facilitate establishment of Quality Risk Assessment (as needed).
- Support process validation lifecycle activities by ensuring a state of control is maintained through ongoing process verification (OPV). Ensure that appropriate variables are identified for on-going monitoring as a contributor to quality risk management activities.
- Author and review process, packaging or cleaning validation protocols & reports, ongoing process and cleaning verification protocols & reports.
- Support execution of validation activities at the shop floor.
- Maintain all activities and projects under own responsibility in an inspection ready status.
- Ensure that all Site validation activities are performed and are in line with the current Novartis requirements and cGMP, manage deviations associated with process validation and makes recommendations for deviation resolution as well as prevention of reoccurrence.
- Participate in pre-validation activities and risk assessments to ensure the success of commercial process validation.
- Other tasks as assigned by the supervisor, and tasks based on a specific appointment.

Essential Requirements:

- BSc. in Chemistry, Pharmacy, Chemical Engineering or Pharmaceutical Technology.
- Fluent in English.
- Knowledge of MS Office.
- Minimum 2-3 years experience in manufacturing/ manufacturing science and technology/technical development/quality.

We offer a **temporary employment for one year** 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 (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.

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

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Innovative Medicines
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Site

Mengeš
Company / Legal Entity
SI19 (FCRS = SI019) Novartis farmacevtska proizvodnja d.o.o.
Alternative Location 1
Warsaw, Pologne
Functional Area
Opérations techniques
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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