Tehnolog proizvodnih procesov II (ž/m/d)/Process Expert II (f/m/d)

Job ID
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Résumé

Kot Tehnolog proizvodnih procesov II za pogoje okolja boste v ospredju pri obvladovanju in kontroli pogojev okolja v čistih prostorih. Pri delu boste planirali in kontrolirali izvedbo vzorčenj, čiščenj, trendirali rezultate, reševali odstope in optimizirali procese na način, da bodo ti zagotavljalji kakovostno in varno proizvodnjo bioloških zdravil.

As a Process Expert II for environmental conditions, you will be at the forefront of managing and controlling environmental conditions in cleanrooms. In your work, you will plan and control sampling, cleaning, trend results, solve deviations, and optimize processes in a way that ensures high-quality and safe production of biological medicines.

About the Role

Vaše ključne odgovornosti:

- Zagotavljanje strokovne podpore na področju vzpostavitve, vzdrževanja in kontrole pogojev okolja v farmacevtski proizvodnji.
- Opravljanje vloge strokovnjaka na svojem področju (SME) za specifične tehnike, izdelke ali tehnološke procese (mikrobiološki in fizikalni pogoji okolja v proizvodnji, postopki vstopa in dezinfekcije, usposabljanje za vzorčenje in aseptične tehnike, planiranje, trendiranje rezultatov, čiščenje in validacije čistih prostorov, validacije avtoklaviranja.
- Usklajevanje in zagotavljanje pravočasnega dokončanja vseh proizvodnih postopkov v skladu z dokumentacijo in pravili dobre proizvodne prakse (GMP).
- Spremljanje rezultatov vzorčenj in ugotavljanje morebitnih trendov ter pravočasno ukrepanje ob opaženih negativnih trendih, priprava periodičnih poročil o izvedenih vzorčenjih.
- Vodenje raziskav odstopov in po potrebi sodelovanje s strokovnjaki relevantnih enot.
- Upravljanje validacij, revalidacij / kvalifikacij ter letnih pregledov procesov v dogovorjenih rokih in po veljavnih predpisih.
- Implementacija in vzdrževanje sistemov kakovosti na lokaciji v skladu s korporativnimi in regulatornimi smernicami ter uvajanje in implementacija novih standardov pri procesih.
- Zagotavljanje ocene tveganj / pomanjkljivosti in določanje učinkovitosti relevantnih korektivnih ukrepov.
- Zagotavljanje splošne pripravljenosti na inšpekcijske preglede ter interne presoje za svoje področje odgovornosti.

Vaš doprinos k delovnem mestu:

- Univerzitetna stopnja izobrazbe iz mikrobiologije, biotehnologije, biologije, farmacevtske tehnologije, kemije, farmacije, inženiringa ali druge ustrezne znanstvene smeri. Zaželen magisterij ali ustrezne izkušnje.
- Zaželeno poznavanje in izkušnje iz farmacevtska proizvodnja, GMP.
- Aktivno znanje angleškega in slovenskega jezika.
- Poznavanje orodij MS Office.
- Odlične komunikacijske veščine, sposobnost samostojnega dela, odločanja ter postavljanja prioritet.

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

English version:

Your key responsibilities:

- Providing professional support in establishing, maintaining, and controlling environmental conditions in pharmaceutical production.
- Acting as a subject matter expert (SME) for specific techniques, products, or technological processes (microbiological and physical environmental conditions in production, entry and disinfection procedures, training for sampling and aseptic techniques, planning, trend analysis of results, cleaning and validation of cleanrooms, autoclave validation).
- Coordinating and ensuring timely completion of all production procedures in accordance with documentation and good manufacturing practices (GMP).
- Monitoring sampling results, identifying potential trends, and taking timely action in case of observed negative trends, preparing periodic reports on conducted sampling.

- Leading investigations of deviations and, if necessary, collaborating with experts from relevant departments.
- Managing validations, revalidations/qualification, and annual process reviews within agreed deadlines and according to applicable regulations.
- Implementing and maintaining quality systems on-site in line with corporate and regulatory guidelines, as well as introducing and implementing new standards for processes.
- Conducting risk/deficiency assessments and determining the effectiveness of relevant corrective measures.
- Ensuring overall preparedness for inspections and internal audits for their area of responsibility.

What you will bring to the role:

- University degree in microbiology, biotechnology, biology, pharmaceutical technology, chemistry, pharmacy, engineering, or other relevant scientific field. Master's degree or relevant experience is desirable.
- Desirable knowledge and experience in pharmaceutical production, GMP.
- Fluent knowledge of English and the local language.
- Proficiency in MS Office tools.
- Excellent communication skills, ability to work independently, make decisions, and prioritize tasks.

We offer **temporary employment of one year with 6 months of probation period**.

Commitment to Diversity & Inclusion:

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

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 (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.

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

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Business Unit
Innovative Medicines
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République de Slovénie
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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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