

Ekspert statistike in proc. analit. teh.

(m/ž/d)/Statistics & PAT Expert (m/f/d)

Job ID
REQ-10048124
Apr 14, 2025
Slovenia

Περίληψη

Iščemo Eksperta statistike in procesnih analitičnih tehnologij, ki bi se pridružil naši ekipi. Zagotavljali boste podporo s statističnimi analizami podatkov in uvedbi procesnih analitičnih tehnologij (PAT) na lokaciji in znotraj globalne mreže z uporabo naprednih in najsodobnejših statističnih načel, orodij in metodologij za izboljšanje razumevanja procesov, kakovosti in skladnosti izdelkov, učinkovitosti in zmogljivosti procesov ter dobičkonosnosti organizacije.

We are looking for a Statistics & PAT Expert to join our team. You will provide excellence in statistical and process analytical technology (PAT) support to the site and within the global network to drive the application of advanced and state-of-the-art statistical principles, tools and methodologies to improve process understanding, quality and compliance of the products, efficiency and capability of the processes and profitability of the organization.

About the Role

Vaše ključne odgovornosti:

- Izvajanje statistične analize podatkov o validaciji procesov za dokazovanje veljavnosti in enakovrednosti.
- Prispevanje k oceni tveganj, kot so FMEA ali matrika tveganj.
- Načrtovanje in vrednotenje načrtov eksperimentov (DoEs) v okviru strategije validacije Novartis Quality by Design.
- Izvajanje analize trendov v okviru stalne verifikacije procesov.
- Uvajanje in uporaba načel statističnega nadzora procesov, vključno z nadzornimi kartami in drugimi tehnikami prepoznavanja vzorcev.
- Omogočanje in podpora multivariatnemu nadzoru procesov, kot je multivariatna analiza podatkov (MVDA).
- Podpora kritičnim preiskavam vzrokov in analizi kompleksnih podatkovnih nizov za hitro preiskavo vzrokov (rRCI).
- Validacija in prenos analitičnih metod, zlasti metod procesne analitične tehnologije (PAT).
- Opremljanje lokacije z naprednimi kompetencami za uporabo statističnih orodij v različnih funkcijah (MS&T, proizvodnja, QA, QC, operativna odličnost) z oblikovanjem in izvajanjem praktičnih usposabljanj

ter zagotavljanjem stalnega mentorstva.

- Omogočanje pobud za izboljšanje procesov v skladu z metodologijami operativne odličnosti, kot so IQP, Six Sigma in Lean Manufacturing.

Vaš doprinos k delovnem mestu:

- Izkušnje z analizo vzrokov (RCA) in korektivnimi ter preventivnimi ukrepi (CAPA).
- Nenehno izboljševanje procesov in statistični nadzor procesov.
- Znanje uporabe statistike, analize podatkov in statistične analize.
- Izkušnje z vitko proizvodnjo, nadzorom procesov in nenehnim izboljševanjem procesov.
- Močno poznavanje GMP, CAPA in obvladovanja tveganj.
- Tekoče znanje angleščine in slovenščine.

Prosimo, da svojo prijavo oddate s slovenskim in angleškim življenjepisom.

Z izbranim kandidatom bomo sklenili delovno razmerje za **nedoločen čas** 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, 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>

Key Responsibilities:

- Conduct statistical analysis of process validation data to demonstrate validity and equivalence.
- Contribute to risk assessments, such as FMEA or risk matrix.
- Plan and evaluate Design of Experiments (DoEs) within the Novartis Quality by Design validation strategy.
- Perform trending analysis as part of Ongoing Process Verification.
- Implement and apply Statistical Process Control principles, including control charts and other pattern

recognition techniques.

- Facilitate and enable multivariate process monitoring and control principles, such as Multivariate Data Analysis (MVDA).
- Support critical root cause investigations and the analysis of complex data sets for Rapid Root Cause Investigation (rRCI).
- Validate and transfer analytical methods, particularly Process Analytical Technology (PAT) methods.
- Equip the Site with advanced applied statistical tool competencies across functions (MS&T, manufacturing, QA, QC, operational excellence) by designing and delivering practical training and providing ongoing coaching.
- Enable process improvement initiatives in alignment with operational excellence methodologies like IQP, Six Sigma, and Lean Manufacturing.

What you will bring to the role:

- Experienced in Root Cause Analysis (RCA) and Corrective Action and Preventive Action (CAPA).
- Continuous Process Improvement and Statistical Process Monitoring.
- Proficiency in Applied Statistics, Data Analytics, and Statistical Analysis.
- Experience with Lean Manufacturing, Process Control, and Continual Improvement Process.
- Strong knowledge of GMP, CAPA, and Risk Management.
- Fluent in English and Slovene.

Please submit your application with a CV in the Slovene and English 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 (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>

Τομέας
Operations
Business Unit
Innovative Medicines
Τοποθεσία
Slovenia
Τοποθεσία
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.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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