

Vodja tehnoloških prenosov (m/ž/d)/Technical Transfer Lead (m/f/d)

Job ID

REQ-10046522

Apr 07, 2025

Slovenia

Summary

V Bioloških učinkovinah Mengeš iščemo vodjo tehnoloških prenosov (ž/m/d), ki bo odgovoren_a za vodenje prenosov tehnoloških postopkov pridobivanja bioloških učinkovin. Delo vključuje vodenje in koordinacijo projektnih aktivnosti, ocenjevanje tehnološke zmogljivosti in izvedljivosti prenosov, pripravo dokumentacije za prenose, ter zagotavljanje učinkovitosti in kvalitete znotraj predvidenih časovnic. Kot vodja tehnoloških prenosov na lokaciji boste odgovorni za vodenje in usmerjanje ekipe strokovnjakov z različnih področij ter sodelovanje z drugimi proizvodnimi lokacijami in razvojnimi organizacijami pri prenosu tehnologij v proizvodnjo. Pridružite se nam v dinamičnem in inovativnem okolju!

English:

At Biološke učinkovine Mengeš, we are looking for a Technical Transfer Lead (m/f/d) who will be responsible for leading the transfer of technological processes for the production of biological substances. The job includes leading and coordinating project activities, assessing technological capacity and feasibility of transfers, preparing documentation for transfers, and ensuring efficiency and quality within the planned timelines. In this role you will be responsible for leading and guiding a team of experts from various fields and collaborating with other production sites and development organizations in transferring technologies into production. Join us in a dynamic and innovative environment!

About the Role

Vaše ključne odgovornosti:

- Odgovorni ste za prenos tehnologije proizvodnje bioloških učinkovin na lokaciji.
- V sodelovanju z drugimi deležniki izdelate oceno tehnične izvedljivosti za odločitev o lokaciji oskrbe, določa obseg in strategijo tehničnih serij za prenos, pripravlja splošno projektno strategijo in projektni načrt, vključno z viri in časovnim okvirom. Sprožite in nadzirate postopek za lokalni nadzor sprememb povezanih s prenosom tehnoloških procesov.
- V primeru pogodbenega sodelovanja zagotavljate skladnost procesov tehnoloških prenosov s pogodbami o kakovosti in poslovnem sodelovanju.
- Oblikujete in vodite projektno ekipo na lokaciji, koordinirate dejavnosti projektne ekipe na lokaciji, povezujete strokovnjake obeh lokacij in poročate projektному vodstvu in vodstvu enote.

- Zagotovite pravočasno razpoložljivost tehnične dokumentacije. Izdelate in uskladite dokumente o prenosu proizvodnega procesa (protokol, poročilo).
- V sodelovanju z drugimi strokovnjaki pregledate in posodobite oceno tveganj kakovost (QRA) pred prenosom in pred validacijo, po potrebi prilagodite strategijo nadzora procesa. Pregledate prvi APQR po prenosu, da zagotovite ustrezno delovanje procesa in kvaliteto izdelka.
- Prispevajte k izboljšanju in optimizaciji procesov za prenose izdelkov.
- Zagotovite, da so na voljo vse ustrezne tehnične informacije in dokumentacija za validacijo.
- Koordinirate izdelavo tehničnih, regulatornih in validacijskih serij na lokaciji v skladu z opredeljeno strategijo validacije. Nudite podporo ekspertu validacij pri ustvarjanju validacijskega protokola in poročila.

Vaš doprinos k delovnem mestu:

- Univerzitetna diploma iz farmacije, farmacevtske tehnologije, kemije, biologije, biotehnologije, inženirskih ved ali drugega ustreznega znanstvenega področja. Zaželen je magisterij ali doktorat.
- Izkušnje pri vodenju tehnoloških projektov v proizvodnji ali razvoju, poznavanje GMP proizvodnje, izkušnje v biotehnološki proizvodnji ali drugih primerljivih industrijah ali institucijah (farmacevtska, živilska, kemijska industrija).
- Projektne vodstvene sposobnosti.
- Močne komunikacijske sposobnosti.
- Znanje angleškega jezika.

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, 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:

Key Responsibilities:

- You are responsible for the transfer of technology for the production of biological substances at the location.
- In collaboration with other stakeholders, you create a technical feasibility assessment for the decision on the supply location, determine the scope and strategy of technical batches for the transfer, prepare the overall project strategy and project plan, including resources and timeline. You initiate and oversee the process for local change control related to the transfer of technological processes.
- In case of contractual cooperation, you ensure compliance of technology transfer processes with quality and business cooperation agreements.
- Form and lead the project team at the location, coordinate the activities of the project team at the location, connect experts from both locations, and report to the project management and unit management.
- Ensure the timely availability of technical documentation. You create and harmonize documents for the transfer of the production process (protocol, report).
- In collaboration with other experts, you review and update the quality risk assessment (QRA) before the transfer and before validation, adjust the process control strategy if necessary. You review the first APQR after the transfer to ensure proper process operation and product quality.
- Contribute to the improvement and optimization of processes for product transfers.
- Ensure that all relevant technical information and documentation for validation are available.
- Coordinate the production of technical, regulatory, and validation batches at the location in accordance with the defined validation strategy. You provide support to the validation expert in creating the validation protocol and report.

What you will bring to the role:

- A university degree in pharmacy, pharmaceutical technology, chemistry, biology, biotechnology, engineering, or another relevant scientific field is required. A master's or doctoral degree is preferred.
- Experience in leading technological projects in production or development, knowledge of GMP production, and experience in biotechnological production or other comparable industries or institutions (pharmaceutical, food, chemical industry).
- Project management skills.
- Strong communication abilities.
- Proficient in 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, 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>

Division

Operations

Business Unit

Innovative Medicines

Location

Slovenia

Site

Mengeš

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.

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