

Znanstveni svetovalec v tehničnem razvoju (m/ž/d) / Senior Expert Science & Technology (m/f/d)

Job ID

REQ-10043602

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Résumé

Več kot 300! Je število navdušenih sodelavcev v analitskem razvoju, ki bolnikom v kliničnih preiskavah zagotavljajo zdravila.

V Razvoju bioloških zdravil Mengeš, na oddelku AO SI v Mengšu, iščemo sodelavca za delovno mesto Znanstveni svetovalec v tehničnem razvoju z vlogo GMP analitskega eksperta. Sodelavec bo odgovoren za načrtovanje strategije, koordinacijo, implementacijo biokemijskih analitskih metod, reševanje kompleksnih analitskih izzivov, z namenom zagotavljanja pravočasne podpore razvojnim projektom v klinični fazi. GMP analitski ekspert bo predstavljal svoj tim v globalnem analitskem projektne timu, kjer bo aktivno podpiral in obvladoval projektne naloge, kot so omogočanje sproščanja kliničnega materiala, izvajanje stabilnostnih študij, podpora oddaji dosjejev in validacije, prenosi in vzpostavljanje analitskih metod v skladu s standardi GMP in dogovorjenimi časovnimi okviri projekta.

About the Role

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Vaše ključne odgovornosti

- Nudenje znanstvenih smernic in vodenje GMP analitskih aktivnosti znotraj globalnega analitskega projektne tima za projekte v klinični fazi.
- Oblikovanje, načrtovanje in koordiniranje analitskih projektne aktivnosti pri razvoju bioloških zdravil. Obvladovanje večjega števila nalog hkrati, zagotavljanje potreb strank.

- Samostojno upravljanje ključnih nalog za sproščanje, stabilitetne študije, validacije, prenose in vzpostavitev analitskih metod.
- Pripravljanje analitske dokumentacije, npr. znanstvenih protokolov in poročil, namenjenih notranjim in zunanjim partnerjem, ter sodelovanje pri pripravi registracijske dokumentacije. Delovati kot ključni analitski ekspert pri inšpekcijah.
- Tolmačenje rezultatov, vrednotenje podatkov, podajanje ustreznih zaključkov. Pregledovanje in potrjevanje podatkov ter kritično vrednotenje rezultatov analiz in eksperimentov, ki so jih opravili drugi sodelavci.
- Aktivno sodelovanje pri pripravi proračuna in načrtovanje virov v sklopu projektnega tima ter upravljanje projektnih časovnic.
- Reševanje kompleksnih problemov na kreativen in učinkovit način
- Aktivno prenašanje znanja in predstavitev znanstvenih ugotovitev znotraj organizacije ter sodelovanje pri optimizaciji delovnih procesov
- Zagotavljanje skladnosti aktivnosti s standardi na področju kakovosti (GMP), na področju zagotavljanja zdravja in varnosti pri delu ter drugimi Novartisovimi standardi.

Minimalne zahteve:

Vaš doprinos k delovnem mestu

- Ekspert farmacevtske tehnologije, biotehnologije, biokemije, kemijskega inženirstva ali druge ustrezne naravoslovne smeri z doktoratom in najmanj 2 leti izkušenj iz področja, ali z magisterijem znanosti in najmanj 6 let izkušenj iz področja.
- Poznavanje analitskih metod, zaželeno v industrijskem okolju, dobro znanje GMP in regulative.
- Sposobnost vodenja in delovanja v več funkcijskih ekipah.
- Odlične sposobnosti sodelovanja in komunikacije (sposobnost učinkovitega sodelovanja z drugimi za doseganje skupnih ciljev s komunikacijo, timskim delom in reševanjem problemov).
- Sposobnost hitrega dojetja novih konceptov, strast do učenja novih stvari.
- Napredno znanje angleškega jezika in dobre predstavitvene sposobnosti.
- Poznavanje digitalnih tehnologij.

Zaželene zahteve:

- Zelo zaželeno močno znanje in izkušnje s projektnim vodenjem ter s področja poznavanja GMP standardov in regulative
- Prednost imajo kandidati z dobrim poznavanjem in z izkušnjami z digitalnimi tehnologijami.

Pričakujemo odgovorne, komunikativne osebe, usmerjene k timskeemu delu in doseganju rezultatov, ki so pripravljene sprejemati nove izzive in stremijo k širitvi svojega znanja.

Ponujamo zaposlitev za **nedoločen čas, s 6 mesečno poskusno dobo**, delo v dinamičnem okolju, sodelovanje z različnimi timi ter izmenjavo znanj in izkušenj znotraj globalnega sistema Novartis.

Zakaj bi se pridružili Novartisu?

750 milijonov. Toliko življenj so se dotaknili naši izdelki. In čeprav smo na to dejstvo ponosni, se moramo v svetu digitalnih in tehnoloških sprememb vprašati: Kako lahko še naprej izboljšujemo in podaljšujemo še več življenj?

Verjamemo, da se odgovori najdejo takrat, ko lahko vedoželjni, pogumni in sodelovanja željni posamezniki – kot si ti – zastavijo nova vprašanja, sprejemajo pogumnejše odločitve in se odločajo tvegati pametneje.

Smo Novartis. Pridruži se nam in pomagaj soustvarjati medicino.

Predani smo raznolikosti in vključenosti:

Novartis se zavzema za raznolikost, enake možnosti in vključenost. Prizadevamo si za oblikovanje raznolikih timov, ki predstavljajo naše bolnike in skupnosti, ki jih oskrbujemo, ter vključujočega delovnega okolja, ki s sodelovanjem razvija drzne inovacije in našim zaposlenim omogoča, da izkoristijo vse svoje potencialne.

Poskrbeli bomo za to, da bodo osebam s posebnimi potrebami zagotovljene primerne prilagoditve pri postopkih za prijavo na delovno mesto ali razgovorih za službo, opravljanju ključnih nalog na delovnem mestu in da bodo deležni drugih prednosti ter ugodnosti pri zaposlitvi.

More than 300! The No. of enthusiastic associates in analytical development in Technical Research and Development Biologics, who brings medicines to patients in clinical trials.

We are seeking for a Senior Expert Science & Technology in Analytical Operations SI in Mengeš with a role of a GMP Analytical Expert. Your main accountability will be to support strategy planning, coordination, implementation of biochemical analytical methods and solving complex analytical challenges in order to provide time efficient support to development projects in the clinical phase. As a GMP Analytical Expert you will be representing GMP analytical function in a global project analytical sub-team, actively supporting and coordinating the GMP-related analytical activities; enabling the release of clinical material, conducting stability studies, supporting submissions and implementation, validation and transfer of analytical methods according to GMP standards and agreed project timelines.

Your key responsibilities

- Provide scientific guidance and lead GMP-related analytical activities within the global project analytical sub-team for assigned projects in the clinical phase.
- Design, supervise and coordinate analytical activities, manage multiple tasks simultaneously, meet customer needs.
- Independently manage key tasks for release, stability studies, validation, transfer and implementation of analytical methods.
- Write analytical documentation, e.g. scientific protocols and reports intended for internal and external partners and support the preparation of registration documents. Act as a key Analytical Expert in audits.
- Evaluate data, interpret results of analyses and draw relevant conclusions. Review and approve data generated by others, critically evaluate results and challenge conclusions made by other scientists.
- Contribute to budget and resource forecast, ensure cost awareness and manage project timelines.
- Communicate, address and solve problems of higher complexity within projects in creative and effective ways.
- Actively drive knowledge sharing and present scientific results across organization and contribute to optimization of work processes.
- Ensure compliance of activities with quality standards (GMP), safety standards (HSE) and other Novartis standards.

Minimum requirements:

What you will bring to the role

- Technical expert in pharmaceutical technology, biotechnology, biochemistry, chemical engineering or other relevant discipline with PhD and 2 years of relevant experience or Master of Science with 6 years of relevant experience.
- Proven experience with analytical methods, preferable in an industrial setting (biotechnology), good knowledge on GMP standards and regulations.
- Ability to work and lead a cross-functional team.
- Demonstrated excellent collaboration and communication skills (ability to effectively work with others to achieve common goals through communication, teamwork, and problem solving).
- Quick learner, able to quickly grasp new concepts, passion for learning new things.
- Strong proficiency in oral and written English and presentation skills.
- Proficient scientific/technical writing skills.

Desirable Requirements:

- Strong knowledge of Project management and GMP standards and regulations would be highly desirable.
- Strong proficiency in digital technologies would be an advantage.

We are looking for responsible, objective-driven candidates who value collaboration, teamwork and are open to new challenges and expanding their knowledge and expertise.

We offer **permanent contract with 6 months of probation period**, work in a dynamic environment, collaboration with different teams, knowledge and experience sharing within the global Novartis system.

Why consider Novartis?

750 million. That's how many lives our products touch. And while we're proud of that fact, in this world of digital and technological transformation, we must also ask ourselves this: how can we continue to improve and extend even more people's lives?

We believe the answers are found when curious, courageous and collaborative people like you are brought together in an inspiring environment. Where you're given opportunities to explore the power of digital and data. Where you're empowered to risk failure by taking smart risks, and where you're surrounded by people who share your determination to tackle the world's toughest medical challenges.

We are Novartis. Join us and help us reimagine medicine.

Commitment to Diversity & Inclusion:

Novartis embraces diversity, equal opportunity and inclusion. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash their full potential.

We will ensure that individuals with disabilities are provided reasonable accommodation to participate in the

job application or interview process, to perform essential job functions, and to receive other benefits and privileges of employment.

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

Development

Business Unit

Innovative Medicines

Emplacement

République de Slovénie

Site

Mengeš

Company / Legal Entity

SI19 (FCRS = SI019) Novartis farmacevtska proizvodnja d.o.o.

Functional Area

Recherche & Développement

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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5. mailto:diversity.inclusion_slo@novartis.com
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