

Znanstveni svetovalec / Senior Expert Science & Technology

Job ID
REQ-10034456

12月 20, 2024

Slovenia

摘要

#LI-Hybrid

We are seeking for a Senior Expert Science & Technology in Analytical Operations SI in Menge š 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.

About the Role

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 offer permanent contract 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 (Energized for Life), employment at Top SI Employer, Unlimited learning and development opportunities.

Commitment to Diversity & Inclusion:

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

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 sprošanja 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.

Vaš 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 sprošanje, stabilizacijo študij, validacije, prenose in vzpostavitve 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 projektne tima ter upravljanje projektne časovnice.

- 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.

Vaš doprinos k delovnem mestu

- Ekspert farmaceutске 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 dojetanja 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 izkušnjami z digitalnimi tehnologijami.

Z izbranim kandidatom bomo sklenili delovno razmerje za nedoločeno obdobje s poskusno dobo 6 mesecev.

Kaj nudimo:

Konkurenčni 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

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>

部门
Development

Business Unit
Innovative Medicines

地点
Slovenia

站点
Mengeš

Company / Legal Entity
SI19 (FCRS = SI019) Novartis farmacevtska proizvodnja d.o.o.

Functional Area
Research & Development

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.inclusionslo@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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