

Analytical Project Lead (m/f/d)

Job ID
REQ-10065324

10月 24, 2025

Slovenia

摘要

Vodja projektov Analitike (m/ ž /d)

#LI-Hybrid

Lokacija / Location: Menge š

Interni naziv pozicije / Internal job title: Znanstveni svetovalec ekspert / Associate Director Science & Technology

We are a global team of highly skilled analytical project managers supporting biologics technical research and development across Novartis sites in Europe. We are seeking an experienced, curious, and inspiring Analytical Project Leader (APL) to join our team and contribute to the growth of our biologic pipeline.

APL serves as the strategic lead for Analytical Development (AD) and is accountable for agreed deliverables to the CMC team and for the scientific quality and content of the development program.

Smo globalna ekipa visoko usposobljenih vodij projektov Analitike, ki podpirajo tehni č ne raziskave in razvoj biolo š kih zdravil na lokacijah Novartisa po Evropi. I š č emo izku š enega, radovednega in navdihujo č ega vodjo projektov Analitike (APL), ki se bo pridru ž il na š i ekipi in prispeval k rasti na š ega portfelja biolo š kih zdravil.

APL je strate š ki vodja za Analitski razvoj (AD) in je odgovoren za dogovorjene rezultate za CMC ekipo ter za znanstveno kakovost in vsebino razvojnega programa.

About the Role

Key Responsibilities:

- Represent Analytical Development on the CMC core team and lead the global analytical sub-team, collaborating with cross-functional partners.
- Lead and coordinate timely delivery of high-quality source documents for regulatory submission (e.g. CMC modules, briefing books) and interact with Health Authorities during audits and scientific advice meetings.
- Communicate proactively on overall project strategy, assess and consolidate analytical resource needs (internal and external) and set priorities accordingly.
- Support and develop sub-team members by fostering growth, motivation, and collaboration through encouraging and servant leadership.
- Lead and manage analytical activities for both drug substance and drug product development, including release and stability testing, API characterization, method-development, -transfer and -validation, specification setting, knowledge and method transfer.
- Critically evaluate data, interpret results and draw relevant conclusions to support product development and regulatory strategy.

Essential Requirements:

- PhD in life science and 8+ years of relevant industry experience, or University degree with significant experience in biologics, pharmaceuticals, or related product development.
- Broad experience in drug development, ideally with biologics or complex molecules.
- Prior experience in analytical development (preferred), formulation, process, or quality within biologics or similar technical area.
- Understanding CMC principles, regulatory expectations, and quality standards in product development.
- Exposure to or familiarity with regulatory submissions (e.g. IND/BLA or equivalent) is a plus.
- Proven ability to lead or coordinate teams/ projects, with 5+ years of leadership or mentorship experience.
- Strong scientific and technical writing capabilities.
- Demonstrated problem-solving, creativity, and productivity in cross-functional environments.
- Demonstrated proficiency in English.

Desirable Requirements:

- Demonstrated excellent communication, presentation and management skills.
- Worked in interdisciplinary teams with excellent theoretical and scientific knowledge of product development.

We are seeking motivated, science-driven professionals who thrive in collaborative environments, value teamwork, and are eager to learn and contribute to innovative biologic therapies.

We offer **permanent employment** with **6 months** of probation period. Submit your application with the CV in Slovenian and English language.

Benefits and Rewards:

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 (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.

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.

Vaš ključ odgovornosti:

- Predstavlja Analitski razvoj v CMC osrednji ekipi in vodi globalno AD podskupino, sodeluje s čezfunkcijskim partnerji.
- Vodi in koordinira pravočasno pripravo visokokakovostnih izvornih dokumentov za regulativne oddaje (npr. CMC moduli, briefing books) ter sodeluje z zdravstvenimi organi med presojami in znanstvenimi svetovanji.
- Proaktivno komunicira o celotni projektni strategiji, ocenjuje in konsolidira potrebe po AD virih (notranjih in zunanjih) ter ustrezno določa prioritete.
- Podpira in razvija člane podskupine z vzpodbujanjem rasti, motivacije in sodelovanja skozi spodbudno vodenje.
- Vodi in upravlja AD aktivnosti za razvoj učinkovine končnega izdelka, vključno s testiranjem sproščenja stabilnosti, karakterizacijo API, razvojem, prenosom in validacijo metod, določanjem specifikacij, prenosom znanja in metod.
- Kritično ocenjuje podatke, interpretira rezultate in izpelje ustrezne zaključke za podporo razvoju izdelka in regulativni strategiji.

Vaš doprinos k delovnem mestu:

- Doktorat iz naravoslovja in 8+ let ustreznih izkušenj v industriji ali univerzitetna diploma z obsežnimi izkušnjami v razvoju bioloških zdravil, farmacevtike ali sorodnih področjih.
- Široke izkušnje v razvoju zdravil, po možnosti bioloških kemikalij kompleksnimi molekulami.
- Predhodne izkušnje v analitskem razvoju (zaželeno), formulaciji, procesu ali kakovosti v

okviru biolo ških zdravil ali podobnih tehni čnih področij

- Razumevanje CMC principov, regulativnih pri črakovanj standardov kakovosti v razvoju izdelkov.
- Poznavanje ali izkušnje s regulativnimi oddajami (npr. IND/BLA ali ekvivalent) so prednost.
- Dokazane sposobnosti vodenja ali koordinacije ekip/projektov, z več kot 5 leti izkušnje v vodenjem ali mentorstvom.
- Mo čne znanstvene in tehni čne sposobnosti.
- Dokazane sposobnosti re ševanja problemov, ustvarjalnosti in produktivnosti v čezfunkcijskih okoljih.
- Dokazana usposobljenost v angle škem jeziku.

Za želenizkušnje

- Dokazane odlične komunikacijske, predstavitvene in vodstvene sposobnosti.
- Delo v interdisciplinarnih ekipah z odličnim teoreti čnim in znanstvenim znanjem razvoja izdelkov.
- Iš čemo motivirane, znanstveno usmerjene strokovnjake, ki uspevajo v sodelovalnih okoljih, cenijo timsko delo in so željuni čenja ter prispevanja k inovativnim biolo škim terapijam.

Z izbranim kandidatom bomo sklenili delovno razmerje za **nedolgo čenč as** poskusno dobo **6 mesecev**. Prijavo oddajte z živiljenjepisomv slovenskem in angleščemjeziku.

Ugodnosti in nagrajevanje:

Konkurenčen plačnik paket, letni bonus, fleksibilen način dela z možnostjo prilagajanja urnika in delom od doma, pokojninska shema, shema nagrajevanja in priznanja dosežkov, razširjeni program promocije zdravja na področju telesnega, duševnega in fizičnega počutja (iniciativa Polni živiljenja), številne priložnosti za učenje in razvoj.

Preberite na špiročnikda spoznate načinę s katerimi bomo spodbujali vašosebni in profesionalni razvoj:

<https://www.novartis.com/careers/benefits-rewards>

Predani smo raznolikosti in vključenosti Novartis

si prizadeva ustvariti izjemno, vključujočedelovno okolje in oblikovanje raznolikih timov, saj ti predstavljajo našbolnike in skupnosti, ki jih oskrbujemo.

Dostop in

prilagoditve: V Novartisu si prizadevamo k vključenostibseb z invalidnostjo in zagotavljanju ustreznih prilagoditev delovnega okolja posameznikom z omejitvami.

V kolikor zaradi bolezni ali invalidnosti potrebujete ustrezne prilagoditve v kateremkoli delu

seleksijskega procesa oziroma potrebujete prilagoditve pri izvajanju osnovnih nalog na delovnem mestu, nam pišite na naslov diversity.inclusionslo@novartis.com in navedite, kakšne prilagoditve potrebujete ter vaše kontaktne podatke. Prosimo, vključite tudi podatek o številkazpisa, na katerega se prijavljate.

Zakaj Novartis: Pomagati bolnikom in njihovim družinam zahteva več kot le inovativno znanost. Potrebna je skupnost zavzetih ljudi, kot ste vi.

V Novartisu cenimo sodelovanje, podporo in navdihovanje drug drugega za razvoj prebojnih terapij, ki spreminjajo življenja pacientov.

Ste pripravljeni ustvariti svetlejšo prihodnost skupaj z nami?

<https://www.novartis.com/about/strategy/people-and-culture>

Pridružite se Novartisu: Ni pravo delovno mesto za vas? Prijavite se v našo bazo talentov, da ostanete v kontaktu z nami in se seznanite z ustreznimi kariernimi priložnostmi, ko se pojavijo: <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>

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

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