

## Znanstveni svetovalec ekspert / Associate Director Science & Technology

Job ID  
REQ-10012490

9月 03, 2024

Slovenia

### 摘要

200! This the current number of programs in clinical development at Novartis. Many of these projects, which include new molecular entities, Biosimilars, as well as additional indications and different formulations for marketed products, are for medicines that could significantly advance treatment standards for patients worldwide.

We are a global team of highly skilled analytical project managers with presence in all biologics technical research and development sites of Novartis in Europe, and we are looking for you as an experienced, curious, inspiring Analytical Project Leader (APL) to join our team to support development of our biologic product pipeline. The APL is the strategic lead of overall analytical development (AD) and is accountable for agreed upon deliverables to the CMC team and the scientific content of development program.

## About the Role

Your key responsibilities are:

- Represent AD on the CMC core team & lead the global analytical sub-team with cross functional members
- Lead and coordinate timely delivery of high quality source documents for submission, review of regulatory documents (e.g. CMC modules, briefing books) and interact with Health Authorities in audits and scientific advice meetings
- Proactively communicate overall project strategy, assess and consolidate resource needs (internal and external costs) and set priorities for the analytical subteam
- Support the growth of the sub-team members and motivates them as appropriate by encouraging and servant leadership
- Lead and manage all analytic related activities of drug product and drug substance development including release and stability-testing, characterization of the API, method-development, -transfer and -validation, specification setting, know-how transfer etc., critically evaluate results and draw relevant conclusions

### Minimum requirements

What you will bring to the role

- PhD and minimum of 8 years relevant experience of Biologics CMC development or University life-science degree with appropriate industry experience
- Previous experience in analytical areas in biologic drug development in an industrial setting
- Excellent understanding of regulatory expectations and requirements with significant experience with IND/ BLA submission
- Proficiency in English
- Proven leader with minimum of 5 years experience in managing teams/ projects
- Proven track record of creativity, problem solving and productivity
- Proficient scientific/technical writing skills

Desirable Requirements:

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

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

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), employment at Top SI Employer, 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>

## Vodja projektov/Analitik - Namestnik direktorja Znan. in teh. (m/ ž /d)

200! To je trenutno število programov, ki so v Novartisovem kliničnem razvoju.

Številni projekti v okviru teh programov vključujejo nove molekularne entitete, podobna biološka zdravila in različne formulacije za izdelke, ki jih tržišimo, in se razvijajo za zdravila, ki utegnejo bistveno izboljšati raven zdravljenja bolnikov po vsem svetu.

Pridružitvi se boste globalnemu timu visoko strokovno usposobljenih vodij projektov - analitikov, ki je prisoten na vseh Novartisovih lokacijah za tehnične raziskave in razvoj bioloških zdravil v Evropi. Iščemo izkušnjeno, vedoželjno, navdihljivo vodjo projektov - analitika (APL) za naš tim, ki bo prispeval pri razvoju bioloških izdelkov. APL je strateški vodja celotnega analitskega razvoja (AD) in je odgovoren za rezultate v skupini CMC ter znanstveno vsebino razvojnega programa

Vaš ključna odgovornosti:

- Zastopanje AD v globalni projektni skupini CMC in vodenje večfunkcijske analitske projektne ekipe
- Vodenje pravočasne priprave visokokakovostne analitske dokumentacije za registracijo zdravil, pregled regulatornih dokumentov (npr. moduli CMC, BB) in sodelovanje z regulatornimi agencijami za zdravila pri presojah in sestankih znanstvenega svetovanja
- Proaktivno komuniciranje celotne projektne strategije, načrtovanje proračuna in virov za AD ter določanje prioritete v analitski projektni ekipi
- Skrb za razvoj članov ekipe, motiviranje s spodbujanjem in vključitvijo vodenje
- Odgovornost za upravljanje vseh dejavnosti razvoja bioloških zdravil, povezanih z analitiko, vključno s sprožitvijo in preskušanjem stabilnosti, karakterizacijo učinkovin, razvojem metod, njihovim prenosom in validacijo, postavitvijo specifikacije, prenosom znanja itd., kritično vrednotenje rezultatov in oblikovanje zaključkov

Vaš doprinos k delovnem mestu:

- Doktorat in najmanj 8 let ustreznih izkušenj razvoja bioloških zdravil ali najmanj univerzitetna izobrazba s področja naravoslovja z ustreznimi izkušnjami v industriji.
- Predhodne izkušnje na področju analitike za razvoj bioloških zdravil v industriji.
- Odlično razumevanje regulative, z znatnimi izkušnjami pridobivanja dovoljenja za klinično preskušanje oz. dovoljenja za uporabo/promet bioloških zdravil.
- Tekoče znanje angleškega jezika.
- Izkušnje z vodenjem; najmanj 5 let izkušenj z vodenjem ekip/projektov.

- Kreativni pristop, veščine uspešnega reševanja problemov in visoka produktivnost.
- Izvrstne veščine znanstvenega/tehničnega pisanja.

Zaželeno izkušnje:

- Odlične komunikacijske spretnosti, veščine predstavljanja in vodenja.
- Izkušnje z delom v interdisciplinarnih ekipah z odličnim teoretičnim in znanstvenim znanjem o razvoju zdravil.

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

Zakaj Novartis?

Naš namen je soustvarjati medicino za izboljšanje in podaljšanje 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 naša 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:

Konkurenčni plačni paket, letni bonus, fleksibeln 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, 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>

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](mailto: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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List of links present in page

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