NOVARTIS

Analytical Project Lead – Associate Director Sci. & Tech. (m/f/d)/Vodja projektov/Analitik – Znanstveni svetovalec ekspert (m/ž/d)

Job ID
REQ-10078713
May 27, 2026
LOC_SI

About the Role

Ključne odgovornosti

• Zastopanje AD v ekipi vodenja projektov ter vodenje globalne analitske podskupine s člani iz različnih funkcij
• Koordinacija analitskih aktivnosti med različnimi deležniki v zgodnjih fazah razvoja bioloških zdravil
• Vodenje in koordinacija pravočasne priprave izvorne dokumentacije za oddajo in pregled regulatornih dokumentov ter sodelovanje z zdravstvenimi oblastmi pri inšpekcijah in znanstvenih svetovanjih
• Proaktivna komunikacija celotne projektne strategije, ocenjevanje in usklajevanje potreb po stroških (internih in eksternih) ter določanje prioritet za analitsko podskupino
• Podpora razvoju članov ekipe ter njihovo motiviranje z ustreznim pristopom (vključno s principom »servant leadership«)
• Vodenje in upravljanje vseh analitičnih aktivnosti, povezanih z razvojem učinkovine in zdravila, vključno s sproščanjem in stabilnostnimi študijami, karakterizacijo API, razvojem, prenosom in validacijo metod, postavljanjem specifikacij, prenosom znanja itd., ter kritično vrednotenje rezultatov in oblikovanje ustreznih zaključkov

Minimalne zahteve

• Doktorat znanosti in najmanj 8 let ustreznih izkušenj na področju razvoja bioloških zdravil ali univerzitetna izobrazba iz področja naravoslovja z ustreznimi izkušnjami iz industrije
• Predhodne izkušnje pri razvoju bioloških zdravil, po možnosti v industrijskem okolju
• Odlično razumevanje razvoja bioloških zdravil
• Zelo dobro znanje angleškega jezika
• Dokazane vodstvene izkušnje z najmanj 5 leti vodenja ekip/projektov
• Dokazana sposobnost kreativnega reševanja problemov in visoka produktivnost
• Odlične sposobnosti znanstvenega/tehničnega pisanja

Zaželene kvalifikacije

• Izkušnje z regulatornimi zahtevami in pričakovanji, zlasti pri oddajah IND/BLA
• Komunikacijske, predstavitvene in vodstvene veščine
• Izkušnje dela v interdisciplinarnih ekipah ter odlično teoretično in znanstveno znanje razvoja izdelkov

Key responsibilities

• Represent AD on the CMC core team & lead the global analytical sub-team with cross functional members
• Coordinate analytical activities between various stakeholders in early-phase development of biologics
• 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, asess 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 development or University life-science degree with appropriate industry experience
• Previous experience in biologic drug development, preferably in an industrial setting
• Excellent understanding of biologics drug development
• Very good proficiency in English
• Proven leadership experience 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

• Previous experience in regulatory expectations and requirements with significant experience with IND/ BLA submission
• Demonstrated excellent communication, presentation and management skills
• Worked in interdisciplinary teams with excellent theoretical and scientific knowledge of product development.

Role Requirements

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

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

Division
DIV_GD
Business Unit
Development
Location
LOC_SI
Site
Mengeš
Company / Legal Entity
SI19 (FCRS = SI019) Novartis farmacevtska proizvodnja d.o.o.
Functional Area
FCT_RD
Job Type
Full time
Employment Type
Regular
Shift Work
No
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