Vodja projektov za farmacevtske izdelke (m/ž/d) / Drug Product Project Lead (m/f/d)

Job ID
REQ-10052525
May 23, 2025
Slovenia

Summary

#LI-Hybrid

Interni naziv / Internal job title: Znanstveni svetovalec (m/ž/d) / Senior Expert Science & Technology (m/f/d)

Smo globalna ekipa visoko usposobljenih vodij projektov za biološke farmacevtske izdelke. Iščemo izkušenega, radovednega in navdihujočega vodjo projektov za farmacevtske izdelke, ki bi se pridružil naši ekipi in podprl razvoj našega portfelja bioloških izdelkov.

Vodja projekta za farmacevtske izdelke je strateški vodja celotnega razvoja bioloških izdelkov in je odgovoren za vodenje razvojnih dejavnosti za sterilne biološke farmacevtske izdelke, ki pokrivajo različne faze razvoja - razvoj formulacije, podporo toksikološkim študijam ter kliničnim študijam , razvoj in karakterizacijo sterilnih proizvodnih procesov, prenos proizvodnih procesov iz laboratorija v proizvodno merilo, podporo validacijskim in registracijskim dejavnostim.

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We are a global team of highly skilled drug product 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 Drug Product Project Leader to join our team to support development of our biologic product pipeline.

The Drug Product Project Leader is the strategic lead of overall drug product development and is accountable for agreed upon deliverables to the Chemistry Manufacturing Controls (CMC) team and the scientific content of development program. The position focuses on leading development activities for sterile biologics drug product covering different phases of the development - formulation development, support to toxicological studies and clinical studies, development and characterization of sterile drug product manufacturing processes, transfer of manufacturing processes from laboratory to production scale, support of validation and registration activities.

About the Role

Vaše ključne odgovornosti:

- Vodenje projektne ekipe za razvoj bioloških farmacevtskih izdelkov, postavitev strategij in koordinacijo vseh aktivnosti za razvoj farmacevtskega izdelka v skladu s tehničnim razvojnim načrtom širšega projektnega tima.

- Določanje prioritet in ciljev projekta za funkcije, ki podpirajo razvoj farmacevtskega izdelka.
- Spremljanje napredka projekta po določenih časovnicah, določanje kritičnih aktivnosti znotraj načrta projekta, identificiranje ovir/tveganj in težav, razvoj rešitev in načrtov za uspešen razvoj farmacevtskega izdelka.
- Postavitev ocene in upravljanje potrebe po virih na projektu (notranji in zunanji stroški).
- Vodenje in upravljanje tehnoloških prenosov proizvodnih procesov farmacevtskih izdelkov iz razvojnih mest na klinične in komercialne notranje/zunanje proizvodne lokacije.
- Kritično ocenjevanje rezultatov/podatkov in postavitev ustreznih zaključkov; nadzor znanstvenih/tehničnih dejavnosti povezanih s projektom.
- Komuniciranje in reševanje kompleksnih nalog (npr. Odstopanja in nepričakovani rezultati iz eksperimentov) znotraj lastnega in širšega področja odgovornosti.
- Koordinacija in pravočasna dostava visokokakovostne izvorne dokumente za oddajo, pregled regulativnih dokumentov (npr. CMC moduli); zagotavljanje odgovorov na vprašanja regulatornih organov.
- Aktivno sodelovanje pri izmenjavi znanja ter mentorstvo sodelavcev.

Vaš doprinos k delovnem mestu:

Iščemo kandidate z dobrimi projektnimi vodstvenimi in organizacijskimi sposobnostmi, komunikacijskimi veščinami, timskim duhom, ki so usmerjeni k rezultatom in odprti za nove izzive v globalnem, medfunkcionalnem okolju.

- Napredna stopnja izobrazbe (zaželeno doktorat) v farmacevtski tehnologiji, biotehnologiji, kemijskem inženirstvu ali drugi ustrezni disciplini;
- Izkušnje (najmanj 5 let) dela v farmacevtski industriji v ustreznih vlogah, npr. Vodja projektov, razvoj formulacij ali proizvodnih procesov, zaželeno znanje o razvoju in proizvodnji za biološka zdravila;
- Razumevanje kakovostnih načel, qbd, gmp, regulativnih vidikov farmacevtske industrije;
- Odlične komunikacijske/prezentacijske veščine in znanstvene/tehnične pisne veščine;
- Aktivno znanje angleškega jezika.

Zaželene izkušnje:

- Vodenje projektnih timov.
- Izkušnje z delom v interdisciplinarnih ekipah z odličnim teoretičnim in znanstvenim znanjem o razvoju zdravil.

Z izbranim kandidatom bomo sklenili delovno razmerje za **nedoločen čas** s poskusno dobo **6 mesecev.** Prijavo oddajte z življenjepisom v slovenskem in angleškem jeziku.

Ugodnosti in nagrajevanje: Konkurenčen plačni 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 življenja), številne priložnosti za učenje in razvoj.

Preberite naš priročnik, da spoznate načine, s katerimi bomo spodbujali vaš osebni in profesionalni razvoj: https://www.novartis.com/careers/benefits-rewards

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 takoj, ko se pojavijo: https://talentnetwork.novartis.com/network

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.

Dostop in prilagoditve: V Novartisu si prizadevamo k vključenosti oseb z invalidnostjo in zagotavljanju ustreznih prilagoditev delovnega okolja posameznikom z omejitvami. V kolikor zaradi bolezni ali invalidnosti potrebujete ustrezne prilagoditve v kateremkoli delu selekcijskega procesa oziroma potrebujete prilagoditve pri izvajanju osnovnih nalog na delovnem mestu, nam pišite na naslov diversity.inclusion_slo@novartis.com in navedite, kakšne prilagoditve potrebujete ter vaše kontaktne podatke. Prosimo, vključite tudi podatek o številki razpisa, na katerega se prijavljate.

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Key Responsibilities:

- Leads the drug product project sub-team and is accountable for the drug product project activities, owns the drug product project strategy in alignment with the technical development plan and represents the project drug product function in the CMC project team;
- Sets priorities and objectives within the drug product sub-team;
- Is responsible for and track project progress according to defined timelines, define the critical path within the sub-team project plan, identify together with the sub-team roadblocks/risks and issues, develop solutions and mitigation plans/scenarios;
- Assesses and consolidates resources needs (internal and external costs)
- Leads and manages the technology transfers of drug product manufacturing processes from development sites and partners to clinical and commercial internal/external manufacturing sites until technical transfer closure.
- Critically evaluation of results/data and drawing relevant conclusions; supervising project related scientific/technical activities; performing complex tasks without having established procedures.
- Communicating, addressing and solving complex problems (e.g. Deviations and unexpected results from experiments) within own and broader area of responsibility.
- Coordination and timely delivery of high quality source documents for submission, review of regulatory documents (e.g. CMC modules, briefing books); provides content to HA questions.
- Actively participates in knowledge exchange and trains and coaches associates and peers with regard to special responsibility.

Essential Requirements:

We are looking for candidates with good project management and organization skills, communication skills, team spirit, who are result driven and open for new challenges in a global, cross-functional environment.

- Advanced degree (desirable PhD) in pharmaceutical technology, biotechnology, chemical engineering or other relevant discipline;
- Experience (minimum 5 years) of work related to pharmaceutical industry experience in relevant roles e.g. project leader, formulation or manufacturing processes development, desirable knowledge in biologics DP development and manufacturing;
- Solid understanding about quality principles, QbD, GMP, regulatory aspects of pharmaceutical industry;
- Excellent communication/presentation;
- Active knowledge of English language.

Desirable Requirements:

- Leading project teams;
- Experience with working in interdisciplinary and cross-cultural teams.

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.

Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

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

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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.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.

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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

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Business Unit
Innovative Medicines
Location
Slovenia
Site
Mengeš
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Research & Development
Job Type
Full time
Employment Type
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Shift Work
No
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