

Višji AS&T specialist (m/ž/d) / Senior AS&T Specialist (m/f/d)

Job ID

REQ-10046554

Apr 01, 2025

Slovenia

Summary

#LI-Hybrid

Kot Višji AS&T specialist boste odgovorni za vodenje analitskih projektov in boste sodelovali s širokim timom strokovnjakov za vzpostavitev analitskih metod za podporo proizvodnji inovativnih bioloških zdravil. Sodelovali boste v strokovni in tehnični podpori na področju analitike, pri odpravljanju kompleksnih težav ter pri upravljanju sprememb.

Če vas veseli delo v dinamičnem okolju, se vidite v projektnem vodenju in želite vseeno ostati vpeti v strokovno delo, se pridružite skupini strokovnjakov v AS&T.

As a Senior AS&T Specialist, you will be responsible for leading the analytical projects and collaborating with a broad team of experts to establish analytical methods to support the production of innovative biological medicines. You will participate in expert and technical support in the field of analytics, in resolving of complex problems and in change management.

If you enjoy working in a dynamic environment, see yourself in project management, and still want to stay involved in an expert role, then join our group of experts in AS&T.

About the Role

Vaše ključne odgovornosti:

- Zagotavljanje podpore transfernim projektom, povezanih s proizvodnjo.
- Odgovornost za strateško planiranje in vodenje analitskih dejavnosti (razvoj, primerjave, validacije in prenosi metod ...) v sodelovanju z drugimi oddelki / funkcijami in projektnimi timi.
- Obvladovanje življenjskega cikla analitskih metod za testiranje izdelkov ter nudenje strokovne in tehnične podpore pri odpravljanju kompleksnih težav, obvladovanju odstopov in sprememb.
- Odgovornost za interpretacijo, statistično vrednotenje in poročanje rezultatov, sprejemanje zaključkov ter priprava poročil.
- Nadgradnja in prenos strokovnih znanj, izobraževanje in razvoj sodelavcev ter odgovornost za osebni in strokovni razvoj.
- Zagotavljanje skladnosti vseh dejavnosti z dobrimi praksami (cGxP), celovitostjo podatkov ter domačo in evropsko zakonodajo, ter sodelovanje pri internih in zunanjih presojah.
- Sodelovanje pri razvoju, implementaciji in nadzoru sistema kakovosti v skladu s slovensko in evropsko

zakonodajo, FDA, mednarodnim svetom za usklajevanje tehničnih zahtev glede zdravil, Konvencijo o farmacevtski inšpekciji in Novartisovimi standardi.

- Odgovornost za kvalifikacijo in kalibracijo opreme ter priprava načrta kvalifikacij opreme.

Vaš doprinos k delovnem mestu:

- Visokošolska stopnja izobrazbe farmacevtske, biološke, kemijske, mikrobiološke ali druge naravoslovne smeri.
- Minimalno 5 let delovnih izkušenj na področju kakovosti, razvoja ali proizvodnje ali drugega ustreznega področja.
- Aktivno znanje angleškega jezika.
- Proaktivnost, samoiniciativnost in hitro dojetje informacij.
- Izkušnje z vodenjem projektne skupine ter delom z več deležniki.
- Aktiven, dinamičen in komunikativen pristop k delu.
- Napredna uporaba Officeovih orodij.

Z izbranim kandidatom bomo sklenili delovno razmerje za **nedoločen čas** s poskusno dobo **6 mesecev**.

Prijavo oddajte z življenjepisom v slovenskem in angleškem jeziku.

Kaj nudimo:

Konkurenčen plačni paket, letni bonus, fleksibilen način dela, z možnostjo prilagajanja urnika in delom od doma, 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.

Key Responsibilities:

- Providing support to transfer projects related to production.
- Responsibility for strategic planning and leading of the analytical activities (development, comparabilities, validations and method transfers...) in collaboration with other departments / functions and project teams.
- Managing of lifecycle of analytical methods for product testing and providing expert and technical support in the resolution of complex problems, control of deviations and changes.
- Responsibility for interpretation, statistical evaluation and reporting of results, drawing conclusions and preparing reports.
- Upgrading and transferring professional knowledge, education and development of colleagues and responsibility for personal and professional development.
- Ensuring compliance of all activities with good practices (cGxP), data integrity and domestic and European law, and participation in internal and external audits.
- Contribution in the development, implementation and assurance of the quality system in accordance with Slovenian and European legislation, the FDA, ICH guidelines, the Inspection Convention and Novartis standards.
- Responsibility for equipment qualification and calibration and preparing an equipment qualification plan.

Essential Requirements:

- Bachelor's degree in pharmaceutical, biological, chemical, microbiological or other natural science direction.
- Minimum of 5 years of work experience in the field of quality, development or production, or other relevant field.
- Active knowledge of the English language.
- Proactivity, self-initiative, and quick comprehension of information.
- Experience in leading project groups and working with multiple stakeholders.
- Active, dynamic and communicative approach to work.
- Advanced use of Office tools.

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

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 (Wellbeing), 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.

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>

Division

Operations

Business Unit

Innovative Medicines

Location

Slovenia

Site

Mengeš

Company / Legal Entity

SI19 (FCRS = SI019) Novartis farmacevtska proizvodnja d.o.o.

Functional Area

Quality

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.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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