

Senior Expert - Extractables and Leachables (m/f/d)

Job ID
REQ-10060712

9月 02, 2025

Austria

摘要

As Senior Expert in the field of Extractables & Leachables (E&L) within Process Analytical Sciences (PAS), you will lead and manage E&L related project activities, applying your scientific expertise across a wide range of E&L relevant fields (e.g. Analytics, Polymer and Materials science). In this role, you will manage operational aspects in close collaboration with internal lab(s) or external partners, within a multidisciplinary project team. You will also contribute to, or lead, initiatives aiming at adapting workflows, E&L testing and risk assessment strategies supporting end-to-end drug development in a context of evolving portfolio and strongly evolving E&L Regulation.

About the Role

Key responsibilities:

- Design, supervise and coordinate E&L related projects activities (incl. risk assessments) for assigned projects. Act as SPOC and SME for assigned projects.

- Run end-to-end E&L studies for container closure systems, manufacturing and administration materials, by applying Liquid injection GC/(HR)MS, Headspace-GC/(HR)MS and HPLC/LC/(HR)MS and other relevant techniques as appropriate, with support of internal labs or external partners (CROs).
- Evaluate, interpret and consolidate results of analyses and draw relevant conclusions (e.g. E&L correlations, consistency of findings vs. tested materials).
- Author and review E&L protocols, reports and assessments intended for internal and external partners and support the preparation of IND/BLA relevant sections as appropriate.
- Support on responses to HAQs as appropriate.
- Communicate, address and solve complex problems within own area of responsibility.
- Ensure effective collaboration with all stakeholders through management of interfaces across functions.
- Actively drive knowledge sharing, present scientific results internally and actively contribute to Novartis relevant networks and workstreams.
- Ensure continuous alignment of own knowledge with the latest regulatory requirements .
- Lead initiatives relevant for the local or global E&L community requiring cross-functional collaboration aiming at adapting ways of working, documentation, testing or assessment strategies.

Essential Requirements:

- University degree (preferably PhD) in Pharmacy, Polymer or Food Chemistry, Life Sciences or other relevant science discipline.
- 8+ years of working experience, preferably in pharma/biopharmaceutical industry or other relevant industry.
- Expertise in at least one of the following analytical technologies: Headspace-GC/MS, LI-GC/(HR)MS, HPLC/(HR)MS, and related sample preparation techniques.
- Excellent scientific writing skills.
- Strong project management skills.
- Excellent communication and collaboration skills.
- Proven ability to lead local or global initiatives.
- Agility, curiosity, product mindset and forward-thinking attitude.

You ' ll receive:

You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. <https://www.novartis.com/careers/benefits-rewards>

In addition to a market-competitive base salary, we offer an attractive incentive program, a modern company pension scheme, childcare facilities, learning and development opportunities as well as worldwide career possibilities within the Novartis group. In accordance with Austrian law, we are obliged to disclose the minimum salary as stated in the collective bargaining agreement. For this position the minimum salary is € 65,605.54 a year (on a full-time basis). The actual salary will be significantly higher, as we strive to maintain a competitive position in the market and consider your previous experience, qualifications and individual competencies.

Commitment to Diversity & Inclusion:

Novartis is committed to building an outstanding, inclusive working environment and diverse teams, representative of the patients and communities we serve.

Adjustments for Applicants with Disabilities

If because of a medical condition, physical disability or a neurodiverse condition you require an adjustment during the recruitment process, please reach out to disabilities.austria@novartis.com and let us know the nature of your request as well as your contact information. The support which we can provide will include advice on suitable positions as well as guidance at all stages of the application process. Austrian law provides candidates the opportunity to involve the local disability representative, Behindertenvertrauensperson (BVP), in the application process. If you would like to request this, please let us know in advance as a note on your CV.

SLO SUMMARY:

Kot vi š ji strokovnjak na področju izlužljivih snovi (E&L) v okviru procesno-analitičnih znanosti (PAS) boste vodili in upravljali projektne dejavnosti, povezane z E&L, pri čemer boste svoje znanstveno znanje uporabljali na širokem naboru področij, povezanih z E&L (npr. analitika, polimeri in znanost o materialih). V tej vlogi boste upravljali operativne vidike v tesnem sodelovanju z internim(-imi) laboratorijem(-i) ali zunanjimi partnerji znotraj multidisciplinarne projektne ekipe. Prispevali boste tudi k pobudam ali jih vodili, katerih cilj je prilagajanje delovnih procesov, testiranja E&L in strategij ocenjevanja tveganj, ki podpirajo razvoj zdravil od začetka do konca v kontekstu razvijajočega se portfelja in močno razvijajoče se uredbe o E&L.

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
Austria

站点
Schaftenau

Company / Legal Entity
AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH

Alternative Location 1
Mengeš, Slovenia

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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