

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

Job ID REQ-10066817

11月 18, 2025

Austria

摘要

#LI-Hybrid

Location: Schaftenau, Austria

About the role

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 HPLCLC/(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.

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

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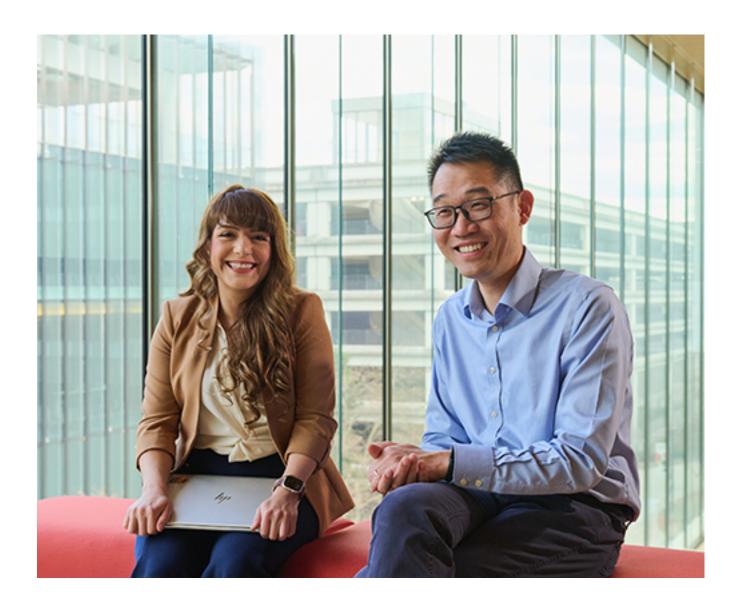
Development

Business Unit

Development
地点 Austria
站点 Schaftenau
Company / Legal Entity AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH
Functional Area Research & Development
Job Type Full time
Employment Type Regular
Shift Work No
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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.

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