

Senior Expert – Process Analytical Sciences (m/f/d)

Job ID
REQ-10056396
Jul 04, 2025
Austria

Summary

#LI-Hybrid

We are seeking a highly skilled and motivated Senior Expert to develop and implement analytical strategies to support late-phase product development and regulatory submissions for accelerated Biologics portfolio projects.

In the role of Senior Expert – Process Analytical Sciences, you will play a key role in driving Extractable and Leachable activities within late-phase development of New Biological Entity and Biosimilar projects. Your primary responsibility is to guide and manage activities within cross-functional project teams.

About the Role

Key Responsibilities:

Your responsibilities include but are not limited to:

- Lead and represent in cross-functional project teams, acting as a single point of contact (SPOC) for all extractable and leachable related topics.
- Plan, manage, and control project resources, schedules, budgets and outsourcing activities.
- Review and Approval of laboratory data, internal and external documents.
- Writing and providing scientific justification for risk assessments, study protocols, study reports in the field of extractables & leachables.
- Ensure compliance with internal process requirements and current regulations.
- Support mock PAI's (Pre-Approval Inspections) and Audits as Subject Matter Expert (SME).
- Prepare Biologics License Application (BLA) Submission relevant reports, assist teams in regulatory dossiers preparation and in responding to health authority questions.
- Proactively lead and drive initiatives independently, taking ownership from concept to execution while ensuring successful outcomes.

Essential Requirements:

- Master or PhD (preferred) in natural science, engineering, pharmaceutical field or equivalent.
- Minimum 3-5 years of experience in the pharmaceutical industry, preferably in Extractables & Leachables and/or late phase development.
- Excellent and extensive analytical understanding, e.g. HS-GC/MS, GC/MS, HPLC/MS.
- Ability to work and lead a cross-functional team in a matrix environment.
- Proven knowledge and track record in project and program planning and execution.

- Understanding and awareness of regulatory standards and guidelines for Extractables and Leachable's, e.g USP <1663>,<1664>,<1665>,<665> , ISO-10993-17, ISO-10993-18.
- Collaborative spirit, self-driven attitude, high level of learning agility, good listening skills, strategic thinker.
- Fluent in German (oral and writing) and English (oral and writing).

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>

Division

Development

Business Unit

Innovative Medicines

Location

Austria

Site

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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6. <mailto:disabilities.austria@novartis.com>
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