

Analytical Project Lead - Associate Director

Job ID REQ-10030421 Nov 22, 2024 Austria

About the Role

Key Responsibilities:

Your responsibilities include, but are not limited to:

- Representing AD on the CMC core team & lead the global analytical sub-team with cross functional members
- Leading and coordinating timely delivery of high quality source documents for submission, review of regulatory documents (e.g. CMC modules, briefing books) and interactions with Health Authorities in audits and scientific advice meetings
- Supporting the growth of the sub-team members and motivating them as appropriate by encouraging and servant leadership
- Leading and managing all analytic related activities of drug product and drug substance development including release and stability-testing, characterization of the active pharmaceutical ingredient (API), method-development, -transfer and -validation, specification setting, know-how transfer etc., critically evaluating results and drawing relevant conclusions
- Communicating effectively across organizational interfaces i.e. project-management, line functions, senior management, etc.
- Proactively identifying scientific, technological and Good Manufacturing Practice (GMP) issues, proposing creative solutions and communicating key issues to the appropriate management level
- Responsibility for analytical budget and resource planning

Essential Requirements:

- PhD and minimum of 8 years relevant experience of Biologics CMC development or University lifescience degree with appropriate industry experience
- Previous experience in analytical areas in biologic drug development in an industrial setting
- Excellent understanding of regulatory expectations and requirements with significant experience with IND/ BLA submission
- Proficiency in English
- Proven leader with minimum of 5 years experience in managing teams/ projects
- · Proven track record of creativity, problem solving and productivity
- Proficient scientific/technical writing skills

Desirable Requirements:

- Demonstrated excellent communication, presentation and management skills
- Worked in interdisciplinary teams with excellent theoretical and scientific knowledge of product

development

Why Novartis?

Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

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 €89,600 per 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.

We are open for part-time and job-sharing models and support flexible and remote working where possible.

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 <u>disabilities.austria@novartis.com</u> 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.

Join our Novartis Network:

If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here:

https://talentnetwork.novartis.com/network

Role Requirements

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

Regulär

Shift Work

No

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