RA CMC Associate Director

Job ID
REQ-10001628

1月 24, 2025

Austria

摘要

Our Development Team is guided by our purpose: to reimagine medicine to improve and extend people ’ s lives.

To do this, we are optimizing and strengthening our processes and ways of working. We are investing in new technologies and building specific therapeutic area and platform depth and capabilities - all to bring our medicines to patients even faster.

As an Associate Director, you will independently, establish and drive strategic and operational global CMC regulatory direction and documentation for projects/products covering development, registration and approval/post approval activities. Make informed regulatory decisions, balancing patient and business risks and benefits leading to timely Health Authority approvals. As an experienced member of the department, facilitate consistency within the CMC regulatory documentation by providing regulatory advice within and outside the department.

We are seeking key talent, like you, to join us and help give people with disease and their families a brighter future to look forward to.

Apply today and welcome to where we thrive together!

About the Role

Major Accountabilities:

- Formulate, lead and drive global CMC regulatory strategy with a focus on innovation, balancing business benefit with regulatory compliance for Biologics and Small Molecules projects/products.
- Lead and implement global CMC submission activities (planning, authoring, reviewing, coordination, submission) for assigned projects/products.
- Identify the required documentation and any content, quality and/or timelines issues for global submissions and negotiate the delivery of approved technical source documents in accordance with project timelines.
- Author and/or review high-quality CMC documentation for HA submission, applying agreed CMC global regulatory strategies, current regulatory trends and guidelines. Ensure technical congruency and regulatory compliance, meeting agreed upon timelines and e-publishing requirements.
- Proactively communicate CMC regulatory strategies, risks and key issues throughout the life cycle in a timely manner to project teams and other stakeholders. Represent department in cross-functional project teams.
- Lead, prepare and communicate CMC risk management assessments and lessons learned on major submissions.
- Initiate and lead Health Authority interactions and negotiations.

Minimum Requirements:

- Education Minimum: Science degree (e.g. Chemistry, Pharmacy, Biochemistry, Molecular Biology, Biotechnology, Biology) or equivalent; advanced degree desired.
- Minimum 8 years of regulatory CMC experience and/or pharmaceutical industry experience.
- Substantial knowledge/experience in regulatory submission and approval processes and ability to deal with complex CMC regulatory issues and requirements.
- Working knowledge of chemistry/biotechnology, analytics or pharmaceutical technology. Proven ability to critically evaluate data from a broad range of scientific disciplines. Knowledge of product development and lifecycle desirable.
- Demonstrated track record to successfully lead/work in interdisciplinary global teams; leading, planning and prioritizing activities simultaneously on multiple projects.
- Regularly demonstrated active contributions to line functions or project teams, as well as contributions to matrix teams with the necessary strategic thinking.
- Demonstrated leadership in a matrix organization, including ability to influence global matrix teams, and provide guidance and direction to team members.
- Demonstrated ability for innovative and big picture thinking. Strong planning, negotiation, organizational and interpersonal skills.
- Computer/IT systems literacy

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: 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 € 78,400/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. 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

Commitment to Diversity & Inclusion: Novartis is committed to building an outstanding, inclusive work 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.

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

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

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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