NOVARTIS

Regulatory Affairs Associate Director, CMC

Job ID
REQ-10077817
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Австрия

Сводка

#LI-Hybrid
Location: Schaftenau, Austria

We are looking for a Regulatory Affairs Associate Director, CMC to contribute to the development and delivery of global Chemistry, Manufacturing and Controls (CMC) regulatory strategies across a portfolio of products.

In this role, you will support regulatory activities across development and lifecycle stages, ensuring high-quality submission content and alignment with global regulatory requirements. Working closely with cross-functional partners, you will help enable timely approvals and maintain compliant, consistent product information across markets.

About the Role

Major Accountabilities

- Contribute to the development and implementation of global CMC regulatory strategies for assigned projects and products.
- Plan, coordinate, and support CMC submission activities, including authoring, review, and submission of documentation.
- Identify documentation requirements and manage alignment on content, quality, and timelines across stakeholders.
- Author and review high-quality CMC regulatory documentation, ensuring compliance with applicable guidelines and standards.
- Communicate regulatory considerations, risks, and updates to cross-functional project teams and stakeholders.
- Contribute to and support Health Authority interactions, including preparation of briefing materials and responses.
- Collaborate across functions to support consistent delivery and alignment on regulatory activities.
- Contribute to continuous improvement initiatives and support knowledge sharing within the regulatory community.

Essential Requirements

- Fluency in English (written and spoken).
- Degree in a scientific discipline (e.g. Chemistry, Pharmacy, Biochemistry, Biotechnology, Biology) or equivalent experience.
- Demonstrated capability in CMC Regulatory Affairs, including regulatory submission and approval processes.
- Strong understanding of CMC regulatory requirements, with the ability to navigate complex regulatory topics and contribute to regulatory strategy.
- Ability to evaluate scientific data across multiple disciplines and translate insights into regulatory decision-making and documentation.
- Working knowledge of pharmaceutical development, manufacturing, or related scientific areas.
- Ability to collaborate effectively and influence within cross-functional, global matrix teams while managing multiple priorities.
- Strong planning, organisational, and interpersonal skills, with a focus on quality, delivery, and continuous improvement.

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 options as well as worldwide career opportunities 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 €78,383.90/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 and Inclusion / EEO paragraph

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.

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

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

Дивизион
Development
Business Unit
Development
Место
Австрия
Сайт

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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Regulatory Affairs Associate Director, CMC

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