NOVARTIS

Regulatory Affairs Manager/Senior Manager, CMC

Job ID
REQ-10076410
Июн. 03, 2026
Австрия

Сводка

#LI-Hybrid (12 days per month on-site)
Office Location: Schaftenau, Austria

Novartis are seeking a Manager/Senior Manager to be responsible for regulatory activities related to Chemistry, Manufacturing and Controls (CMC), including the preparation and publication of CMC regulatory documentation for Health Authority submissions. The role also involves engaging with Health Authorities on CMC-related questions to support both new product launches and post-marketing activities.

About the Role

Major Accountabilities:

- Formulate, lead and drive global CMC regulatory strategy with a focus on innovation, balancing business benefit with regulatory compliance.
- 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.

Essential Requirements:

- Science degree (e.g. Chemistry, Pharmacy, Biochemistry, Molecular Biology, Biotechnology, Biology) or equivalent.
- Minimum 5 years of regulatory CMC experience and/or pharmaceutical industry experience.
- Demonstrated knowledge/experience in regulatory submission and approval processes and ability to deal with complex CMC regulatory issues and requirements.
- Proven ability to critically evaluate data from a broad range of scientific disciplines.

Benefits & Reward:

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 €65,605.54/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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