

Regulatory Affairs CMC Manager

Job ID
REQ-10043473

Mar 25, 2025

Austria

Summary

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.

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!

As manager, you provide strategic and operational global CMC regulatory direction and documentation for our products covering development and post-approval activities. You bring regulatory knowledge regarding drug development, manufacturing, and analytical testing, as well as a collaborative and patient-focused mindset.

About the Role

Major accountabilities:

- Formulate and lead 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.
- 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
- Ideally, at least 2 years' experience in regulatory CMC experience and/or pharmaceutical industry experience; working knowledge in regulatory submissions desirable.
- Demonstrated working knowledge of chemistry/biotechnology, analytics or pharmaceutical technology. Knowledge/experience of regulations, guidelines and product life cycle

maintenance desirable.

- Ability to critically evaluate data from a broad range of scientific disciplines.

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 €64 023,54 /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. 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>

部門

Development

部門

Innovative Medicines

国

Austria

勤務地

Schaftenau

Company / Legal Entity

AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH

Functional Area

Research & Development

職種

Full time

雇用形態

Regular

Shift Work

No

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List of links present in page

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2. <https://www.novartis.com/careers/benefits-rewards>
3. <https://www.novartis.com/about/strategy/people-and-culture>
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