Regulatory Affairs CMC Senior Manager

Job ID
REQ-10060701

9月 03, 2025

Austria

摘要

#LI-Hybrid (3 days per week on-site)
Location: Schaftenau, Austria

As a Senior Manager, you ' ll drive global strategic and operational CMC regulatory direction across the full product lifecycle – from development to post-approval. Bring your deep regulatory expertise in drug development, manufacturing, and analytical testing, and collaborate with cross-functional teams to deliver patient-focused solutions that matter.

About the Role

Major Accountabilities:

- **Drive Global CMC Strategy:** Take the lead in shaping and executing innovative global CMC regulatory strategies for Biologics and Small Molecules – balancing business impact with

regulatory excellence.

- **Own Submission Success:** Lead end-to-end global CMC submission activities – from planning and authoring to coordination and delivery – ensuring timely, high-quality submissions that meet Health Authority expectations.
- **Navigate Documentation with Precision:** Identify and manage documentation requirements, resolve content and timeline challenges, and negotiate the delivery of approved technical source documents aligned with project milestones.
- **Craft Regulatory Excellence:** Author and review top-tier CMC documentation for global submissions, applying strategic insights, regulatory trends, and technical accuracy – all while meeting e-publishing standards and deadlines.
- **Be the Voice of CMC Strategy:** Proactively communicate regulatory strategies, risks, and key issues across project teams and stakeholders throughout the product lifecycle. Represent the department in cross-functional teams with confidence.
- **Lead Risk Management & Lessons Learned:** Champion CMC risk assessments and share critical learnings from major submissions to continuously improve regulatory processes and outcomes.
- **Engage with Health Authorities:** Initiate and lead impactful interactions and negotiations with global Health Authorities, driving alignment and regulatory success.

Minimum Requirements:

- Science degree (e.g. Chemistry, Pharmacy, Biochemistry, Molecular Biology, Biotechnology, Biology) or equivalent; advanced degree desired.
- 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.

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 € 58,500/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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