RA CMC Senior Manager

Job ID
REQ-10021216
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Autriche

Résumé

Verantwortlich für regulatorische Aktivitäten insbesondere in den Bereichen Chemie, Herstellung und Kontrolle (CMC). Aktivitäten wie die Vorbereitung und Veröffentlichung von REG CMC-Dokumentation für Einreichungen bei Gesundheitsbehörden. Interagieren Sie außerdem mit HA's auf REG CMC-Fragen, um neue Produkte oder Markteinführungen zu unterstützen.

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 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 €63,600/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.

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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

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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

Division
Development
Business Unit
Innovative Medicines
Emplacement
Autriche
Site
Schaftenau
Company / Legal Entity
AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH
Functional Area
Recherche & Développement

Job Type
Full time
Employment Type
Regulär
Shift Work
No
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Unterstützungen für BewerberInnen mit Behinderungen

Wenn Sie aufgrund einer Erkrankung, einer körperlichen Behinderung oder eines neurodiversen Zustandes eine Unterstützung bei terschiedlichen Teilen des Rekrutierungsprozesses benötigen, wenden Sie sich bitte an disabilities.austria@novartis.com und teile n Sie uns die Art Ihrer Anfrage sowie Ihre Kontaktinformationen mit. Unsere Unterstützung umfasst die Beratung zu geeigneten Positionen sowie die Begleitung bei allen Phasen des Bewerbungsprozesses. Das österreichische Gesetz sieht die Möglichkeit vor, die örtliche Behindertenvertrauensperson (BVP) in das Bewerbungsverfahren einzubeziehen. Wenn Sie dies wünschen, teilen Sie uns dies bitte vorab als Vermerk in Ihrem Lebenslauf mit.

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