RA CMC Manager - Cell & Gene Therapies

Job ID
REQ-10058954

7月 29, 2025

Austria

摘要

583! That is the total number of projects and products on our Global Regulatory Affairs CMC project list. All of these innovative projects are aimed at making a difference in patients ’ lives and we need your help. 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

RA CMC Manager - Cell & Gene Therapies

Your Responsibilities include but are not limited to:

- Formulate and lead global CMC regulatory strategy with a focus on innovation, balancing business benefit with regulatory compliance for Cell & Gene Therapy 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.

What You'll Bring To The Role

- Ability to work successfully with global project teams and prioritize activities considering timelines and workload
- Well-developed planning, organizational, negotiation, problem solving and interpersonal skills
- Good oral and written communication skills with a collaborative and patient-focused mindset
- Computer/IT systems literacy

Desirable 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

Apply to Job

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.

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Job ID
REQ-10058954

RA CMC Manager - Cell & Gene Therapies

Apply to Job

Source URL:
https://www.novartis.com.cn/careers/career-search/job/details/req-10058954-ra-cmc-manager-cell-gene-therapies

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://www.novartis.com/careers/benefits-rewards
3. https://www.novartis.com/about/strategy/people-and-culture
4. https://talentnetwork.novartis.com/network
5. https://www.novartis.com/careers/benefits-rewards
6. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Schaftenau/RA-CMC-Manager---Cell---Gene-TherapiesREQ-10058954-1
7. mailto:disabilities.austria@novartis.com
8. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Schaftenau/RA-CMC-Manager---Cell---Gene-TherapiesREQ-10058954-1