Regulatory Affairs CMC Associate Director

Job ID
REQ-10011560
Jun 28, 2024
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!

About the Role

Major accountabilities:

. Formulate, lead and drive global CMC regulatory strategy for Biologics or Small Molecules projects/products drawing on substantial regulatory expertise with a focus on innovation, maximizing the business benefit balanced with regulatory risks and compliance.

• Lead and drive all global CMC submission activities (planning, authoring, reviewing, coordina-tion, submission) for assigned projects/products, while applying the global strategy into submis-sions.

• Identify the required documentation and any content, quality and/or timeliness 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 Health Authority submissions, estab-lishing and applying CMC global regulatory strategies, current regulatory trends and guidelines. Ensure technical congruency and regulatory compliance, meeting agreed upon timelines and e-publishing requirements.

• Represent Global Regulatory CMC on cross-functional project teams and maintain collaborative partnerships with stakeholders

• Initiate and lead Health Authority interactions and negotiations: setting objectives, preparing briefing books, coordinating and planning rehearsals and risk mitigation plans. Establish and maintain a single point of contact with FDA.

• Provide strategic advice and direction within the department and cross-functionally through specialized assignments.

Minimum Requirements:

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

• Minimum 8 years regulatory experience preferred and/or pharmaceutical industry experience

• Substantial 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: 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

Commitment to Diversity & Inclusion:

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

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

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Division
Development
Business Unit
Innovative Medicines
Location
Austria
Site
Schaftenau
Company / Legal Entity
AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work

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Regulatory Affairs CMC Associate Director

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