NOVARTIS

Regulatory Affairs CMC Associate Director (Oncology)

Job ID
REQ-10050927

May 16, 2025

USA

Summary

Independently, establish and drive strategic and operational global CMC regulatory direction and documentation for projects/products covering development, registration and approval/post approval activities. Make informed regulatory decisions, balancing patient and business risks and benefits leading to timely Health Authority approvals.
As an experienced member of department, facilitate consistency within the CMC regulatory documentation by providing regulatory advice within and outside the department.

About the Role

Key Responsibilities:

- Formulate, lead and drive global CMC regulatory strategy 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, coordination, submission) for assigned projects/products, while applying the global strategy into submissions.
- 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, establishing 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.
- 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 and boards as appropriate.
- Lead, prepare and communicate CMC Risk Management Assessments, contingency plans and lessons learned on major submissions and escalate as appropriate.
- 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.
- Represent department on due diligence teams for in-licensing and divestment opportunities.
- Participate on teams for continuous improvement within and outside the department to improve working practices and processes.
- Provide strategic advice and direction within the department and cross functionally through specialized assignments.

Essential Requirements:

- Science Degree (e.g. Chemistry, Pharmacy, Biochemistry, Biotechnology, Biology) or equivalent. Desirable: Advanced Science Degree
- Minimum 8 years in regulatory preferred, and/or experience in pharmaceutical industry.
- Substantial knowledge/experience in regulatory submission and approval processes and ability to deal with complex CMC regulatory issues and requirements.
- Working knowledge of chemistry/biotechnology, analytics or pharmaceutical technology. Proven ability to critically evaluate data from a broad range of scientific disciplines. Knowledge of product development and lifecycle desirable.
- Demonstrated track record to successfully lead/work in interdisciplinary global teams; leading, planning and prioritizing activities simultaneously on multiple projects.
- Regularly demonstrated active contributions to line functions or project teams, as well as contributions to matrix teams with the necessary strategic thinking.
- Demonstrated leadership in a matrix organization, including ability to influence global matrix teams, and provide guidance and direction to team members.
- Demonstrated ability for innovative and big picture thinking.

Desirable Requirements:

- Strong planning, negotiation, organizational and interpersonal skills.
- Computer/IT systems literacy

The pay range for this position at commencement of employment is expected to be between $138,600 and $257,400 /year; however, while salary ranges are effective from 1/1/25 through 12/31/2025, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an "at-will position" and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

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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

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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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Accessibility & Reasonable Accommodations

The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area
Research & Development

職種
Full time

雇用形態
Regular

Shift Work
No

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