NOVARTIS

Regulatory Affairs Associate Director, CMC

Job ID
REQ-10078161
май 29, 2026
Швейцария

Сводка

#LI-Hybrid
Location: Basel, Switzerland

We are looking for a Regulatory Affairs Associate Director, CMC to contribute to the development and delivery of global Chemistry, Manufacturing and Controls (CMC) regulatory strategies across a portfolio of products.

In this role, you will support regulatory activities across development and lifecycle stages, ensuring high-quality submission content and alignment with global regulatory requirements. Working closely with cross-functional partners, you will help enable timely approvals and maintain compliant, consistent product information across markets.

About the Role

Major Accountabilities

- Contribute to the development and implementation of global CMC regulatory strategies for assigned projects and products.
- Plan, coordinate, and support CMC submission activities, including authoring, review, and submission of documentation.
- Identify documentation requirements and manage alignment on content, quality, and timelines across stakeholders.
- Author and review high-quality CMC regulatory documentation, ensuring compliance with applicable guidelines and standards.
- Communicate regulatory considerations, risks, and updates to cross-functional project teams and stakeholders.
- Contribute to and support Health Authority interactions, including preparation of briefing materials and responses.
- Collaborate across functions to support consistent delivery and alignment on regulatory activities.
- Contribute to continuous improvement initiatives and support knowledge sharing within the regulatory community.

Essential Requirements

- Fluency in English (written and spoken).
- Degree in a scientific discipline (e.g. Chemistry, Pharmacy, Biochemistry, Biotechnology, Biology) or equivalent experience.
- Demonstrated capability in CMC Regulatory Affairs, including regulatory submission and approval processes.
- Strong understanding of CMC regulatory requirements, with the ability to navigate complex regulatory topics and contribute to regulatory strategy.
- Ability to evaluate scientific data across multiple disciplines and translate insights into regulatory decision-making and documentation.
- Working knowledge of pharmaceutical development, manufacturing, or related scientific areas.
- Ability to collaborate effectively and influence within cross-functional, global matrix teams while managing multiple priorities.
- Strong planning, organisational, and interpersonal skills, with a focus on quality, delivery, and continuous improvement.

Commitment to Diversity and Inclusion / EEO paragraph

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

Accessibility and Accommodation

Novartis is committed to working with and providing reasonable accommodation to all individuals. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to receive more detailed information about the essential functions of a position, please send an e-mail to inclusion.switzerland@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

Дивизион
Development
Business Unit
Development
Место
Швейцария
Сайт
Basel (City)
Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG
Functional Area
Research & Development
Job Type

Full time
Employment Type
Regular
Shift Work
No

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