NOVARTIS

Regulatory Affairs Manager/Senior Manager, CMC

Job ID
REQ-10079740
Июн. 17, 2026
Швейцария

Сводка

#LI-Hybrid (12 days per month on-site)
Office Location: Basel, Switzerland

Novartis are seeking a Manager/Senior Manager to be responsible for regulatory activities related to Chemistry, Manufacturing and Controls (CMC), including the preparation and publication of CMC regulatory documentation for Health Authority submissions. The role also involves engaging with Health Authorities on CMC-related questions to support both new product launches and post-marketing activities.

About the Role

Major Accountabilities

- Formulate, lead and drive global CMC regulatory strategy with a focus on innovation, balancing business benefit with regulatory compliance.
- 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.

Essential Requirements

- Science degree (e.g. Chemistry, Pharmacy, Biochemistry, Molecular Biology, Biotechnology, Biology) or equivalent.
- 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.

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)

Primary location salary range
CHF93,800.00 - CHF174,200.00
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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