

# Regulatory Affairs CMC Senior Manager

Job ID  
REQ-10011561  
Sep 02, 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.

As senior manager, you independently provide strategic and operational global CMC regulatory direction and documentation for our products covering development and post-approval activities. You bring a foundation of regulatory knowledge regarding drug development, manufacturing, and analytical testing, as well as a collaborative and patient-focused mindset.

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 with a focus on innovation, balancing business benefit with regulatory compliance for Biologics and Small Molecules 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.
- Lead, prepare and communicate CMC risk management assessments and lessons learned on major submissions.

- Initiate and lead Health Authority interactions and negotiations.

Minimum Requirements:

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

**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>

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

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

No

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