# Regulatory Affairs CMC Senior Manager - Biologics " >

Job ID
312782BR
USA

## Job Description

582! That is the total number of projects and products on our Global Regulatory Affairs CMC project list. All of these innovative projects are aimed at making a difference in patients' lives and we need your help. 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 and a collaborative, patient-focused mindset.

Your Responsibilities include, but are not limited to:
• Formulate, lead and drive global CMC regulatory strategy with a focus on innovation, balancing business benefit with regulatory compliance for 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.

## Diversity & Inclusion / EEO

*The Novartis Group of Companies are Equal Opportunity Employers and take pride in maintaining a diverse environment. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, gender, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash their full potential.*

## Minimum Requirements

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Division
Global Drug Development
Business Unit
REG AFFAIRS GDD
Location
USA
Site
East Hanover, NJ
Company / Legal Entity
Novartis Pharmaceuticals
Functional Area
Research & Development
Job Type
Full Time
Employment Type
Regular
Shift Work
No

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