Gbl Program Regulatory Director (Early Development -Gen Meds) - Remote " >

Job ID
320562BR
Jun 04, 2021
USA

Job Description

8 Disease areas. 95 NMEs. 45 associates worldwide. That is Regulatory Affairs Early Development in 2021. Novartis Institutes for Biomedical Sciences (NIBR) is world-renowned for its groundbreaking science in drug development including cell and gene therapy. We work closely with scientists in NIBR on innovative medicines in diseases with a high unmet medical need based on NIBRs scientific discoveries. As part of the NIBR team, Early Development Regulatory Managers contribute to bring innovative novel therapies to patients as quickly as possible. We are a culturally diverse, highly collaborative, curious and unbossed team who play a critical role planning for first in human and to optimize strategies from first in human to the development decision point, as well as contribute to the long-term strategy of the projects to registration in collaboration with RA colleagues in Global Drug Development. Read on to learn what you could do as part of our closely knit team and join us at the scientific frontier!

This role can be based at either the East Hanover, NJ or Cambridge, MA sites

This position can be based remotely anywhere in the U.S. (there may be some exceptions based on legal entity registration). Please note that this role would not provide relocation as a result. The expectation of working hours and travel (domestic and/or international) will be defined by the hiring manager.

Your Responsibilities Include, but are not limited to:

• Provide regulatory leadership to assigned project(s)

• Develop high quality and globally aligned regulatory strategies to achieve optimal development objectives and life cycle management plans

• Ensure that Regional/CPO input is sought and incorporated into global regulatory strategy

• Evaluate and clearly communicate to management regulatory risks/gaps and trade-offs for the overall development plan and develop mitigation/contingency plans for identified risks

• Responsible for development and implementation of the global strategic regulatory plan

• Leverage regional expertise in executing globally aligned regulatory strategies, and ensure timely sharing of program changes/information to support timely communication to Health Authorities globally

• Partner with regions to align on strategy in order to fulfill business objectives

• Acquire timely consultation with RA line management and Novartis advisory boards on strategy

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

What You'll Bring to the role:
• Science based BS or MS with requisite experience and proven capability. Advanced degree (MD, Ph D, PharmD) preferred

• Experience with regulatory submission, HA negotiations and approval processes in major regions

• Minimum 6-8 years of regulatory and drug/biologic development experience, ideally spanning activities in Phases I-IV in most or all of the following areas:
o Innovation in regulatory strategy.
o 2-5 years of proven leadership and accomplishment in all aspects of regulatory affairs in a global/matrix environment in the pharmaceutical industry.
o Global matrix management experience desirable.
o Good management, interpersonal, communication, negotiation and problem solving skills.
o Good organizational awareness (e.g., interrelationship of departments, business priorities), including experience working cross functionally and in global teams, and collaborating effectively with external development partners.
o Experience in medical device and/or digital device registration is an asset

Why consider Novartis?

769 million. That’s how many lives our products touched in 2020. And while we’re proud of that fact, in this world of digital and technological transformation, we must also ask ourselves this: how can we continue to improve and extend even more people’s lives?

We believe the answers are found when curious, courageous and collaborative people like you are brought together in an inspiring environment. Where you’re given opportunities to explore the power of digital and data. Where you’re empowered to risk failure by taking smart risks, and where you’re surrounded by people who share your determination to tackle the world’s toughest medical challenges.

Imagine what you could do at Novartis!

Commitment to Diversity & Inclusion:

Novartis embraces diversity, equal opportunity and inclusion. 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.

Join our Novartis Network:

If this role is not suitable to your experience or career goals but you wish to stay connected to learn more about Novartis and our career opportunities, join the Novartis Network here:

https://talentnetwork.novartis.com/network
Division
Global Drug Development
Business Unit
REG AFFAIRS GDD
Location
USA
Site
Cambridge, MA
Company / Legal Entity
Novartis Pharmaceuticals
Functional Area
Research & Development
Job Type
Full Time
Employment Type
Regular
Shift Work
No
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