NOVARTIS

Global Regulatory Affairs Manager

Job ID
REQ-10058240

7月 23, 2025

USA

摘要

#LI-Hybrid #LI-Onsite

In this role, you will be a part of the Regulatory team within Navigate and will be primarily responsible for providing strategic product direction as well as directing and coordinating the submission of regulatory documents for regulated IVD products in development. This role will actively participate on project teams, identifying gaps or risks, with the goal of ensuring regulatory compliance to ensure timely approval of new medical device clinical studies, continued approval of investigational IVD studies, through filing and approval of new medical devices (IVDs).

About the Role

Your Key Responsibilities:

- Actively creates, approves and submits regulatory documents including significant risk

determination (SRDs), Investigational Device Exemption (IDEs), and Performance Study Applications (PSA), Annex XIV documentation and Institutional Review Board (IRB) submissions, briefing books, progress reports, amendments, supplements, substantial modifications, summary documents and correspondence directly or through legal representative
- Drives coordination and planning of all activities associated with submissions, including preparation of regulatory documents to ensure timely completion and submission of dossiers with adherence to timelines worldwide. Develops and implements plans to avoid/minimize clock stops during submission review
- Provides strategic product direction to teams on interaction and negotiates evidence with regulatory agencies. Includes providing advice to development teams on manufacturing changes, impact assessments, technical labeling, appropriate regulations and interpretations. Provides input into and implements regulatory strategy and manages operational activities for assigned projects globally
- Interacts and negotiates with regulatory agency personnel to expedite approval of pending registration and answers any questions. Develops and implements plans for timely response to health authority requests and coordinates responses
- Primary contact for and manages relationship with global regulatory consultants and legal representatives, charged with communications, regulatory filings, timing, etc. to ensure compliance with relevant health authorities.
- Maintain and leverage data and metrics for efficient management of regulatory activities within and across projects
- Implements policies, procedures and best practices for regulatory affairs, collaborates with cross-functional teams within business units to develop and execute regulatory strategies from product inception to product launch. Serves as a regulatory liaison on the project team throughout the product lifecycle.
- Demonstrates good judgment in selecting methods and techniques for obtaining solutions. Erroneous decisions result in critical delays and modifications to projects or operations; cause substantial expenditure of additional time, human resources, and funds; and jeopardize future business activity
- Provides project management services as needed to support regulatory/GXP projects

Essential Requirements:

- BS or MS in a scientific discipline, with 5+ years or direct regulatory experience with 3+ years experience in IVD
- Ability to write high quality submission documentation
- Ability to handle multiple tasks and to prioritize and schedule work to meet business needs
- Ability to identify areas of concern in moderately complex projects and lead changes
- Excellent communication, organization and time management skills
- Functional breadth of knowledge and ability to apply sound judgment and discretion
- Strong business mindset, interpersonal skills, critical thinking skills and resilience

Desired Requirements:

- Project Management and/or IVD assay development experience
- Clinical and/or compliance experience

The salary for this position is expected to range between $114,100 and $211,900 per year.

The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors.

Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards.

US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we ' ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status.

Accessibility & Reasonable Accommodations

The Novartis Group of Companies are committed to working with and providing reasonable

accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

部门
Operations

Business Unit
Universal Hierarchy Node

地点
USA

状态
California

站点
Carlsbad

Company / Legal Entity
U441 (FCRS = US441) Navigate BioPharma Services, Inc.

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

Apply to Job

Job ID
REQ-10058240

Global Regulatory Affairs Manager

Apply to Job

Source URL:
https://www.novartis.com.cn/careers/career-search/job/details/req-10058240-global-regulatory-affairs-manager

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. mailto:us.reasonableaccommodations@novartis.com
5. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Carlsbad/Global-Regulatory-Affairs-ManagerREQ-10058240-1
6. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Carlsbad/Global-Regulatory-Affairs-ManagerREQ-10058240-1