Director, Regulatory Affairs Advertising & Promotion

Job ID
REQ-10060211

8月 29, 2025

USA

摘要

Novartis has an incredible opportunity for a talented individual to join our team as the Director, Regulatory Affairs Advertising & Promotion. You will provide strategic regulatory advice on advertising/promotion and medical materials to the US organization for assigned products, including launch products/indications, or complex and/or high-priority products in accordance with business goals and objectives, FDA regulations/guidances, PhRMA guidelines, and company policy.

This position will be located at the East Hanover site and will not have the ability to be located remotely. This position will require 20% travel as defined by the business (domestic and/ or international).

Please note that this role would not provide relocation, and only local candidates will be considered.

About the Role

Key Responsibilities:

- Serves as a primary regulatory advertising and promotion reviewer for assigned products on Materials Approval Process ("MAP") teams, including launch products/indications, or complex and/or high-priority products
- Liaison with OPDP regarding advertising and promotion for assigned products, including products approved under Subpart H. Establishes strong and positive working relationship with OPDP reviewers. Manages OPDP queries on assigned products.
- Applies regulatory and therapeutic area knowledge to Brand Team's objectives and initiatives to develop solutions to complex US promotional issues. Ensures regulatory compliance while effectively managing business risks.
- Maintains awareness of competitive activities by monitoring major US Medical meetings where assigned therapeutic area products are promoted.
- Prepares complaint letters to OPDP.
- Conducts reviews of materials to be used by medical personnel in discussions with customers.
- Serves as Regulatory Affairs representative on cross-functional committees, task forces, etc.
- Monitors US regulatory promotional environment by reviewing regulatory promotional guidelines, untitled and warning letters to pharmaceutical companies published by OPDP, and by attendance of major FDLI, DIA and other industry/FDA meetings.
- Collaborates with other Regulatory Affairs colleagues to provide input to study designs or US label regarding feasibility of promoting potential data/claims.
- Participates in US labeling negotiations and FDA meetings as necessary.
- Ensures that changes in US Prescribing Information are reflected in current promotions and advertising.

Essential Requirements:

- BS Degree or equivalent. Advanced degree desirable (MS, PhD, PharmD, or JD)
- Minimum 5 years regulatory experience in the pharmaceutical space
- In-depth knowledge and understanding of US regulations for drug promotion/advertising and US labeling
- Experience in leading activities for OPDP submissions, including time of first use sub-missions, requests for advisory comments, and 30-day submissions for Subpart H products
- Experience with regulatory activities involved in a product or indication launch
- Proven ability to analyze and interpret efficacy and safety data
- Understanding of business goals of the in-volved business franchise, marketing concepts and tools
- Must perform independently with strong negotiation and decision-making skills
- Must be able to work in a multi-disciplinary environment
- Proven analytical and problem-solving skills associated with problem review and inquiries and proven ability to provide creative solutions to complex problems

Novartis Compensation Summary:

The salary for this position is expected to range between $176,400 and $327,600 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
US

Business Unit
Universal Hierarchy Node

地点
USA

状态
New Jersey

站点
East Hanover

Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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