Regulatory Policy & Intelligence Director

Job ID
REQ-10043175
Mar 25, 2025
USA

Summary

Regulatory Policy Director leads the development, implementation, and monitoring of regulatory policies and strategies by shaping with evolving regulatory requirements. This role involves advising senior management on regulatory issues, fostering relationships with regulatory authorities and industry stakeholders, and integrating regulatory considerations into business planning and decision-making.

About the Role

#LI-Hybrid

Key Responsibilities:

- Provide regular communications and briefings to Global and Regional Policy Heads on relevant global regulatory policy issues
- Participate in internal product team meetings to provide regulatory policy context for business decision
- Provide strategic regulatory advice to Regulatory Affairs (RA) colleagues on drug development projects and registration, and marketed products in preparation for Health Authority (HA) meetings.
- Develop training materials and participate as a facility member on new and emerging regulatory requirements for RA colleagues and other line functions
- Analyze impact of important emerging regulatory policies and new requirements on Novartis projects and business
- Prepare and coordinate internal stakeholder feedback on proposed laws, regulations and guidances, to ensure consideration of Novartis positions by trade organizations
- Represent Novartis on external committees e.g. trade associations
- Collaborate with Novartis Public Affairs to shape emerging legislative proposals
- Identify and escalate key information as appropriate within RA, Global Drug Development and other internal stakeholders
- Coordinate and lead internal cross-functional groups/task forces on implementation of regulatory guidelines in new and emerging areas.

Key Performance Indicators (KPIs)

- Develop strategic policy plans and create innovative regulatory solutions to support RA project teams.
- Proactively shape the external environment to support Novartis development and regulatory strategic priorities.
- Lead and manage small teams of regulatory and other Development professionals, via a matrix environment, at a high performance level.
- Ensure internal stakeholder alignment on business critical regulatory policies

- Enable Novartis reputation externally as a credible, ethical and preferred partner

Essential Requirements:

- Science-based, health policy or legal studies BS or MS with requisite experience and demonstrated capability. Advanced degree (MD, Ph D, PharmD) desirable
- 6-8 years of regulatory and drug/biologic development experience, Health Authority experience desirable
- Demonstrable history of success over multiple years in a regulatory or health policy role with a strong understanding of regulatory and legislative environment
- Command of the drug development process, pharmaceutical business
- Knowledge and experience with local regulatory affairs and regulations
- Organizational awareness (e.g., interrelationship of departments, business priorities), including experience working cross functionally and in global teams.
- Ability to enable teams to think strategically, creatively and proactively
- A flexible, positive and creative thinker with the proven ability to develop and implement innovative policy strategies and processes
- Good management, interpersonal, communication (both verbal and written), negotiation and problem-solving skills

The pay range for this position at commencement of employment is expected to be between $176,400 and $327,600 /year; however, while salary ranges are effective from 1/1/25 through 12/31/2025, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an “at-will position” and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

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