

Head, RA Intelligence

Job ID
REQ-10046639

4月 10, 2025

United Kingdom

摘要

The Director of Regulatory Intelligence is responsible for leading the company's efforts to stay ahead of evolving global regulatory environments and will drive a consistent practice to regulatory intelligence globally, resulting in a proactive and forward-thinking approach to regulatory challenges. The Director, Regulatory Intelligence will provide Regulatory Intelligence oversight and evaluate the impact of emerging regulatory requirements on the company's portfolio. This role will ensure that the latest regulatory intelligence is incorporated into the portfolio and support internal and external policy advocacy activities.

About the Role

Major accountabilities:

- Lead the Regulatory Intelligence team within the RA Policy & Intelligence organization to monitor and analyze emerging global regulations, guidelines, and trends that impact the

industry.

- Provide actionable communications to RA leadership and cross-functional teams on regulatory developments that could influence the company ' s strategy, product portfolio, and business objectives.
- Manage and coordinate the research of relevant laws, guidelines and initiatives and lead the development of regulatory intelligence frameworks and processes to integrate these insights into decision-making, ensuring the company stays ahead of regulatory changes.
- Collaborate with internal Policy teams to provide regulatory advice and align regulatory intelligence strategies with business goals, including timely escalation of emerging information as appropriate.
- Prepare and coordinate internal stakeholder feedback on proposed laws, regulations and guidance in collaboration with Policy colleagues, to ensure consideration of Novartis positions by trade organizations
- Manages public consultation procedures for EU and US as well as ensure coordination across regions to ensure a consistent One Novartis voice.
- Oversee the development and execution of training programs in collaboration with PTC to ensure that teams remain current with evolving and emerging regulatory requirements.
- Participate on internal Working Groups to evaluate impact of important regulatory requirements for Novartis projects and ensure that regulatory intelligence is effectively communicated and integrated into risk management, operational planning, and long-term strategic initiatives.
- Contribute to internal knowledge management systems including curation of regulatory policy positions, policy & intel training materials, KPI metrics, and related processes.
- Lead and mentor a team of Regulatory Intelligence professionals, fostering a culture of collaboration, innovation, and continuous improvement.

Key performance indicators:

- Timeliness of regulatory Insights: Ensure regulatory intelligence reports or updates are delivered ahead of key milestones (i.e. product development phases, submission deadlines)

- Quality and relevance of regulatory intelligence: Feedback from cross-functional teams and leadership on the accuracy, relevance and applicability of regulatory insights that contribute to successful achievement of business goals.
- Regulatory risk mitigation: All major regulatory risks are identified, and intelligence is shared to support early intervention or proactive strategy adjustments.
- Stakeholder engagement and Influence: Successful engagements with regulatory agencies or industry groups that influence regulatory intelligence strategy or enhance the company ' s regulatory standing
- Training and knowledge dissemination: Ensure regulatory intelligence training sessions are held, and all required personnel are trained annually and well-informed about regulatory changes.

Minimum Requirements:

Work Experience & Skills:

- Minimum 6-8 years of regulatory and drug/biologic development experience, Health Authority experience desirable.
- Science based, health policy or legal studies BS or MS preferred, Advanced degree (MD, PhD, PharmD desirable)
- 2-3 direct reports; additional matrix leadership across policy team for intelligence responsibilities
- Demonstratable history of success over multiple years in 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, 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 regulatory intelligence strategies and processes

- Good management, interpersonal, communication, negotiation and problem-solving skills
- People management experience; may include management in a matrix environment.
- Must be fluent in English

This role offers hybrid working and will require 3 days per week or 12 days per month in our London Office.

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部门
Development

Business Unit
Universal Hierarchy Node

地点
United Kingdom

站点
London (The Westworks)

Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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