

Executive Director, Regulatory Operations

Job ID
REQ-10060882

9月 01, 2025

United Kingdom

摘要

#LI-Hybrid (12 days per month on-site)
Location: London (The Westworks), United Kingdom
Internal Job Title: Head of Regulatory Operations

As a pivotal senior leadership role within the Regulatory Affairs (RA) and Enabling Functions (EF) organization, the Head of Regulatory Operations will lead the strategic direction and execution of Novartis' global Regulatory Operations capabilities. This includes submission management, document standards, publishing, structured data submissions, and submission intelligence. You will be at the helm of planning, tracking, and managing the regulatory lifecycle for our diverse global portfolio, ensuring seamless delivery and compliance across markets. This is a unique opportunity to drive innovation, operational excellence, and strategic impact at scale.

About the Role

Key responsibilities:

- Global Leadership & Organizational Excellence: Establish and evolve a best-in-class Regulatory Operations (RO) organization, driving performance, accountability, and a culture of continuous improvement.
- Strategic Submission Oversight: Approve and guide strategies to elevate the quality and efficiency of Development registration dossiers, including NDAs, MAAs, and major supplements/variations.
- Patient-Centric Impact: Champion submission plans that promote execution excellence, maximize content re-use, and enable simultaneous health authority reviews—advancing global patient equity.
- Portfolio Accountability: Align teams with business frameworks to ensure clear ownership and continuity across submission management activities.
- Digital Transformation & Innovation: Spearhead automation and digitalization initiatives, ensuring RO technologies are business-aligned, well-supported, and future-ready.
- Health Authority Engagement: Lead direct interactions with global Health Authorities to negotiate e-submission strategies and resolve validation issues, ensuring successful application acceptance.
- Industry Leadership & Future-Fit Models: Monitor regulatory trends and implement innovative operating models that position Novartis at the forefront of regulatory excellence.
- External Influence & Advocacy: Represent Novartis in Health Authority forums and industry working groups, shaping evolving regulatory guidelines and submission strategies.
- Global Standards & Compliance: Define and implement harmonized global standards and processes to ensure consistent regulatory submission compliance across markets.

Essential Requirements:

- Industry Expertise: Extensive experience in the pharmaceutical industry, with a strong background in global Regulatory Operations or equivalent functions.
- Strategic Leadership: Demonstrated success in guiding large, geographically dispersed teams, providing clear strategic direction and fostering a high-performance culture.
- Global Submission Mastery: Proven track record of leading high-priority initial applications and executing rapid globalization strategies within a major pharmaceutical organization.
- End-to-End Drug Development Knowledge: Deep understanding of the drug development lifecycle, pharmaceutical business dynamics, and strategic portfolio management.
- Executive Presence: Senior leadership experience with exceptional communication, negotiation, and stakeholder engagement skills, including representation at Executive Committees.
- People Leadership: Strong capability in managing, mentoring, and developing talent, with a focus on building resilient, empowered teams.
- Innovative Mindset: A creative and forward-thinking approach to problem-solving, with a passion for driving continuous improvement and innovation.
- Results Orientation: A proactive, transparent, and accountable working style, with the ability to deliver under pressure and navigate complexity with confidence.

Commitment to Diversity and Inclusion/EEO

Novartis is committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

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>

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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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