International Regulatory Excellence Director

Job ID
REQ-10061872

10月 01, 2025

United Kingdom

摘要

#LI-Hybrid (12 days per month on-site)
Location: London (The Westworks), United Kingdom

The International Regulatory Excellence Director (IRED) International Regulatory Excellence Director role will act as a strategic leader, guiding country regulatory operations across an assigned international region–driving compliance, operational efficiency, and process innovation. You ’ ll lead the design and implementation of regional processes, support regulatory actions that enable business operations, and partner globally to resolve compliance challenges and shape preventive risk management strategies. This role also plays a key part in supporting health authority inspections and ensuring follow-through on resulting measures. Join us to influence global standards, elevate regulatory excellence, and make a meaningful impact across diverse markets.

About the Role

Major accountabilities:

- Accountable that country/regional regulatory requirements and perspective are represented and acknowledged during global process design or update. Represents RA International countries on global regulatory process review and approval boards, global cross functional initiatives and committees, whenever required.
- Is accountable to build a structured network of active stakeholders across International countries and global functions to address potential quality issues / emerging compliance and recommend solutions.
- Provides guidance and support to country operations during design of local or regional processes. Supports countries in evaluating and implementing changes to local or regional processes stemming from various sources, including but not restricted to changes in the regulatory legislation, internal tools and business practices.
- Ensures an up-to-date curricula for regional roles and supports country regulatory teams in designing country level roles and curriculae.
- Lead and / or support initiatives to optimize working models and compliance in their assigned region. Ensure implementation of global RA compliance strategies and cross-functions risk management framework across International countries, thereby further enhancing core business processes at the country level.
- Support the management of local or regional Quality Incidents/Quality Events - perform investigation, root cause analysis, support CAPA preparation and effectiveness checks across countries in International, as needed. Ensure Inspection readiness.
- Support to local CO audits / inspection / self-assessment in regions, as needed.
- Responsible for escalating issues to management as necessary and according to process.

Essential Requirements:

- Bachelor ' s science-based degree required with requisite experience and demonstrated capability. Higher degree preferred.
- Fluent in English. Other languages is an advantage.
- A wealth of experience in Pharma, Regulatory Affairs, Quality Assurance, Audit/Inspection management support, Risk Management, Project Management.
- Extensive knowledge and experience of worldwide regulations, guidelines and regulatory processes.
- Advanced ability to drive outcomes in cross-functional teams in a matrix environment.
- Proven records of process simplification and optimization.
- Advanced analytical skills and ability to understand/predict impact of process and systems
- Proven records of excellent interpersonal, communication, influencing and negotiation skills, and proven ability to work effectively in a cross-functional and international matrix environment.
- Highly experienced in change management, intercultural experience, and ability to act in a complex and rapidly changing business environment.
- Strong quality focus, influencing, communication skills, and experience in data analytics and risk management.

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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