Associate Director, Regulatory Affairs (Medical Devices)

Job ID
REQ-10064221

10月 13, 2025

United Kingdom

摘要

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

The Associate Director, Regulatory Affairs (Medical Devices) independently provides strategic and operational global medical device regulatory direction and documentation for projects/products covering design and development, registration, approval and post approval activities.

You will make informed, compliant regulatory decisions, balancing patient and business risks and benefits leading to timely Health Authority approvals.

About the Role

Major accountabilities:

- Develop and communicate RA MD regulatory strategies for projects across the life cycle (Development and On-Market).
- Ensure device regulatory risks and key issues are communicated in a timely manner to project teams and other stake holders. Represent department in cross-functional project teams as appropriate.
- Provide Novartis technical functions clear, concise guidance on current device regulatory requirements to support planning and decision making.
- Lead and implement global Regulatory Affairs Medical Device (RA MD) submission activities (planning, authoring, reviewing, coordination, submission) for assigned projects/products.
- Identify the required documentation and content, compliance and timelines issues for global submissions and work collaboratively with cross-functional teams for the delivery of technical source documents in accordance with project timelines.
- Author and/or review compliant RA MD documentation for HA submissions, applying agreed RA MD Global regulatory strategies, current regulatory standards and guidelines.
- Lead, prepare and communicate RA MD risk management assessments, contingency plans, and lessons learned on major submissions and escalate as appropriate.
- Facilitate/support device related interactions with Health Authorities globally.
- Contribute to knowledge sharing, e.g. provide coaching within RA CMC and other functional areas
- Contribute to the development of new guidance, policy, and processes.

Minimum requirements:

- Experience in Medical Device Regulatory Affairs.
- Significant experience in the combination product or medical device industry.
- Proven knowledge of regulatory submission and approval processes for medical devices and combination products.
- Ability to critically evaluate data across diverse scientific disciplines.
- Understanding of product development and lifecycle management.
- Demonstrated success in leading and prioritizing multiple projects in global, cross-functional teams.
- Strong independent working skills with the ability to manage timelines and workload effectively.
- Excellent planning, organizational, and interpersonal skills.
- Proficiency in computer and IT systems.

Commitment to Diversity & Inclusion

Novartis is committed to building an outstanding, inclusive work environment and diverse team ' s 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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