Global Program Regulatory Manager (Neuroscience)

Job ID
REQ-10044622

3月 26, 2025

United Kingdom

摘要

As Global Program Regulatory Manager, you will work with the support of a RA Program Lead to develop and implement the global regulatory strategy for program(s) through development, registration and post approval in the assigned region(s). The Global Program Regulatory Manager is also a member of the Regulatory Affairs sub team and may lead or represent RA in regional or cross functional teams.

About the Role

Key Responsibilities:

Regulatory Strategy

- Provide input to global program regulatory strategy, including regulatory designations & innovative approaches

- Coordinates regulatory readiness with other line functions, Country Organizations & Regions, representing Regulatory Affairs (RA) or leads in regional RA or cross-functional activities providing strategic input into cross functional deliverables
- Contributes to the development and maintenance of key documents, determines the requirements and coordinates the activity for Health Authority (HA) interactions

Regulatory Submissions

- Leads planning, preparation and submission of clinical trials.
- Leads implementation of the defined global registration strategy into regional submissions worldwide by country organizations
- Coordinates, plans and prepares for submission of initial registrations and post approval applications, and the preparation, review and maintenance of local product information as assigned
- Lead regulatory activities during HA reviews, responding to questions and HA interactions

Regulatory Excellence & Compliance

- Ensures timely RA input and submission of regulatory compliance and maintenance reports, maintaining regulatory information in compliance databases and document management systems

Essential Requirements:

- Science based BS or MS with requisite experience and demonstrated capability. Advanced degree (MD, Ph D, PharmD) preferred.
- Experience with regulatory submission and approval processes in 1 or more major regions.
- Experience in a global/matrix environment or cross- functional teams in the pharmaceutical industry.
- Experience in HA negotiations.

- 2-4 years involvement in regulatory and drug/biologic development spanning activities in Phases I-IV in the following areas:
- Innovation in regulatory strategy
- Understanding of post-marketing/brand optimization strategies and commercial awareness preferred
- Involvement in dossier submissions and approvals | HA negotiations | Drug regulatory submission and commercialization in region
- Analysis and interpretation efficacy and safety data
- Regulatory operational expertise
- Strong interpersonal, communication, negotiation and problem-solving skills
- Basic organizational awareness (e.g., interrelationship of departments, business priorities).

Location: UK, London Hybrid working requirement 3 days / 12 days per month in office.

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部门
Development

Business Unit
Innovative Medicines

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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