

Global Program Regulatory Manager

Job ID
REQ-10051722

5月 27, 2025

United Kingdom

摘要

Our Development Team is guided by our purpose: to reimagine medicine to improve and extend people's lives. To do this, we are optimizing and strengthening our processes and ways of working. We are investing in new technologies and building specific therapeutic area and platform depth and capabilities - all to bring our medicines to patients even faster. 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).

About the Role

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 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 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.

Your Experience:

- Science based bachelors degree, plus an understanding of pharmaceutical development, clinical trials.
- Track record of involvement in regulatory or pharmaceutical development, in one or more major regions.
- Strong interpersonal skills and experience working in a complex, cross functional organization and leading cross function teams.
- Compliance and Quality mindset.
- Fluency in English.

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

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>

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.

Join our Novartis Network:

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Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <https://www.novartis.com/careers/benefits-rewards>

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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