Global Program Regulatory Manager - Life Cycle Management

Job ID
REQ-10011606

9月 25, 2024

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.

We are seeking key talent, like you, to join us and help give people with disease and their families a brighter future to look forward to.

Apply today and welcome to where we thrive together!

The Role:

This role offers hybrid working, requiring 3 days per week in our London office.

As Global Program Regulatory Manager - Life Cycle Management, 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 - LCM Management is also a member of the RA sub team and may lead or represent RA in regional or cross functional teams.

About the Role

Major accountabilities:

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. May facilitate HA meetings or act as local HA liaison respectively.

Regulatory Submissions

- Leads planning, preparation and submission of clinic trails, and the implementation of defined global registration strategy into regional submissions worldwide with country organsiations.

- 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.

Life Cycle Management

- You may also focus on one of the following key areas of activity:

- Maintenance - preparation of selected global regulatory submissions.

- Portfolio Transformation - e.g. streamlining activities, divestment/ integration, portfolio transformation and manufacturing transfer.

- Business & Operational Excellence - collating, for example, registration samples, CPPs etc. to support submissions.

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.

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:

Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/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
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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