NOVARTIS

Senior Global Program Regulatory Manager

Job ID
REQ-10016663
Nov 06, 2024
Reino Unido

Resumen

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!

This role offers hybrid working, requiring 3 days a week / 12 days a month based in office.

As Senior Global Program Regulatory Manager, you will work with limited supervision to develop and implement the global regulatory strategy for program(s) through development, registration and post approval in the assigned region(s). You may act as the RA program lead on programs of limited complexity.

The Senior Global Program Regulatory Manager is also a member of the RA sub team and may lead or represent RA in regional or cross functional teams. You may also act as a subject matter expert and/or assume a mentoring role.

About the Role

Major Accountabilities:

Regulatory Strategy

- Provide input to global program regulatory strategy, including regulatory designations & innovative approaches and may provide global RA leadership for specific part of the program or act as lead for a program of limited complexity.
- 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 lead or serve in HA meetings or 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.
- May serve as a RA subject matter expert and assume a mentoring role.

Life Cycle Management

- You may also focus on one of the following key areas of activity:
- Maintenance – review & sign off of selected global regulatory submissions.
- Portfolio Transformation – e.g. streamlining activities, divestment/ integration, portfolio transformation and manufacturing transfer.

Your Experience:

- Science based bachelors or advanced degree, plus advance understanding of pharmaceutical development, clinical trials.
- Awareness of post marketing/ brand optimization strategy, with track record of involvement in regulatory or pharmaceutical development in Phases I – IV, in multiple geographies.
- 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

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

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

División
Development
Business Unit
Innovative Medicines

Ubicación
Reino Unido
Sitio
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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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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