Senior Global Program Regulatory Manager

Job ID
REQ-10016663
Nov 06, 2024
United Kingdom

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.

Role Requirements

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Division
Development
Business Unit
Innovative Medicines
Location
United Kingdom
Site
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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