

# Senior Global Program Regulatory Manager

Job ID  
REQ-10011584  
Jul 03, 2024  
United Kingdom

## Summary

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 join us in reimagining new medicines together! The Role: This role offers hybrid working, requiring 3 days per week in our White City, London 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.

### Regulatory Submissions

- Leads planning, preparation and submission of clinical trials.
- Leads implementation of the defined global registration strategy into regional submissions

- Leverage scientific knowledge and acumen in the analysis, interpretation and communication of data to colleagues
- 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.

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## **Your Experience:**

- Science based bachelor's or advanced degree, plus advance understanding of pharmaceutical development, clinical trials.
- Awareness of post marketing/ brand optimization strategy
- 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>

## **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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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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