RA Manager

Job ID
REQ-10030086
Dec 23, 2024
Türkiye

Summary

-Directs the development of submission of product registration, progress reports, supplements, amendments, and/or periodic experience reports. Provides strategic product direction to teams on interaction and negotiates evidence with regulatory agencies. Interacts and negotiates with regulatory agency personnel in order to expedite approval of pending registration and answers any questions. Serves as a regulatory liaison on the project team throughout the product lifecycle. Ensures rapid and timely approval on of new drugs, biologics/biotechnology and/or medical devices and continued approved status of marketed drugs or medical devices. Serves as regulatory representative to marketing or research project teams and government regulatory agencies. Provides advice to development and/or marketing teams on manufacturing changes, line extensions, technical labeling, appropriate regulations and interpretations. Coordinates, reviews, and may prepare reports for submission.

About the Role

Major accountabilities:

- Is responsible for implementing regulatory strategy and managing operational activities for assigned major/ large regions.
- Reporting to Country RA Director and will be responsible for managing RA Specialists for different therapeutic areas
- Provides input into global regulatory strategy and contributes to Regulatory Functional Plan (RFP) and Seed Document, or their equivalents, including identification of gaps or risks in global strategic plan for assigned regions.
- Partners with regions to align on regulatory strategy in order to fulfil business objectives -Implements RFP across assigned regions.
- Determines requirements and sets objectives for Health Authority (HA) interactions with DRA GPT representative and/or GTAL.
- Facilitates preparation and finalization of briefing books and contributes to preparation of summary documents.
- Develops and implements plans for timely response to HA requests and coordinates responses.
- May serve as local HA liaison depending on location (e.g., FDA or EMA).
- Drives coordination, planning, and submission of dossiers in assigned regions worldwide.
- Review of global dossier summary documents.
- Develops and implements plans to avoid/minimize clock stops during submission review.
- Reviews, approves and submits Clinical Trial Applications (CTAs) and Investigational New Drugs (INDs).
- Reviews and submits Risk Management Plans.
- May lead negotiations for regional approvals independently or with DRA GPT representative and/or

GTAL.

- Responsible for facilitating timely submission and approval of dossier with HAs under the guidance of the DRA GPT representative and/or GTAL.
- Contributes to and often leads the development of departmental goals and objectives.
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Key performance indicators:

- Successful implementation of global regulatory strategy for timely submissions and approvals with the best possible labels based on available data.
- Identification of main HA issues -Participation in relevant regulatory Boards leading to valuable input from these Boards.
- Successful Participation in HA interactions to achieve business objectives.
- Adherence to Novartis policy and guidelines -Project & stakeholder feedback

Minimum Requirements:
Work Experience:

- Cross Cultural Experience.
- At least 3 years team management experience & 5 years regulatory affairs experience
- Functional Breadth.
- Project Management.
- Operations Management and Execution.
- Representing the organization.

Skills:

- Clinical Trials.
- Cross-Functional Teams.
- Detail Oriented.
- Drug Development.
- Lifesciences.
- Negotiation Skills.
- Problem Solving Skills.
- Regulatory Compliance.
- Risk Management.

Languages :

- English.

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professionally: https://www.novartis.com/careers/benefits-rewards

Division
Development
Business Unit
Innovative Medicines
Location
Türkiye
Site
Istanbul Ataşehir
Company / Legal Entity
TR01 (FCRS = TR001) Novartis Sağlık, Gıda ve Tarım Ürünleri San. Ve Tic. A.Ş.
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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