Assistant Manager - Regulatory Affairs

Job ID
REQ-10048070

4月 09, 2025

India

摘要

-Ensures a controlled documentation system, record retention, and information services including electronic records retention processes in accordance with regulatory requirements. Ensures compliance to the requirements from regulatory agencies. Maintains the technical and non-technical documentation change system. Assures procedures are in place to classify and maintain records. Interprets & enforces all documentation formatting, standards, policies, and operating procedure requirements. May identify submission components, communicate documentation standards and coordinate assembly of regulatory dossiers. May analyze and evaluate data, extract pertinent information, prepare information abstracts and executive summaries of material searched. May maintain extensive knowledge of product information and continuous contacts with local, regional, and divisional customers.

About the Role

Major accountabilities:

- · Compilation and HA submissions of New Drug applications, Line extensions, additional indications along with the site registrations, renewals and production transfer applications for Novartis Pharma products and demonstrate independent working with minimum supervision from manager.

· Compilation and HA submission of Clinical Trial Application (CTA) dossiers for GDO projects as per defined timelines along with their compliance activities Novartis India Public Affairs for monitoring progress to take next actions steps as appropriate in consultation with RA, GDD Manager/ Head.

· For assigned TAs support in developing and implement regulatory strategy for pipeline products and flawless execution of agreed strategy. Expedite launches for early access & benefits to India patient.

· Assist managers to design strategies to handle critical applications like legal entity name change of foreign sites, change in Indian agent, warehouse transfers, production transfers, BRS changes etc. to ensure no gap in supplies of essential medicines.

· Maintenance of compliance activities like PSUR, Post approval changes like CMCs and pack insert updates of drug products and their HA submissions.

· Maintenance of on-going CT projects: Independently, ensure various regulatory compliances related to the clinical trial projects from submission to study completion.

· Timely review and approval of commercial and clinical applications as and when required

· Interact with local SSO group for finalization of texts related to clinical trial consignment labels / licences and ensuring that the same are implemented for timely and smooth clearance of clinical trial materials.

· Review of protocol, investigator brochure, IMPD documents and entire clinical trial package and co-ordinate with local GDO group to ensure completeness for timely HA submission.

· Responsible for cross-functional coordination (with Legal, Local SSO, Public Affairs) regarding obtaining/renewal of approvals/licenses as applicable of the CT projects.

· Develop and maintain good working relationships with other related departments within Novartis India.

· Provide intra/inter departmental regulatory support in terms of information/documents to meet SSO team needs.

· Provide need-based training/information/guidance on regulatory requirements/ updated regulations to associates and stakeholders and as requested by Manager, RA, GDD /Head.

· Independently track, maintain stipulated regulatory requirements /updates regarding the said projects to HA, pre and post submission phase.

· Assist Head / Manager, RA, GDD for regulatory intelligence; as appropriate

· People management - Guiding/coaching/mentoring RA Executives and resolving their queries

· Active participation in cross-functional meetings such as namely Supply Chain Meeting, Global CMC & PIE for impactful collaboration.

· Co-ordinate with stakeholders for SEC presentations and timely response to HA queries.

· Represent India as the Policy Champion and ensure all local regulations are assessed and timely implemented as applicable.

Key performance indicators:

- · Timely submission of CT applications.

· Timely submission of related follow-up information/documents/ regulatory compliances for maintenance of clinical trial approvals.

· Timely approvals for New Drug applications, Line extensions, additional indications.

· Timely submission and approval for site registrations and the renewed site registration certificate along with test license

· Timely submission of PSURs and safety label changes.

· Ensure innovative ways to handle challenging regulatory scenario for commercial e.g. (facilitate CDTL/IPC testing and ensure timely receipt of reports, innovative submission, SEC excellence etc)

· Ensure adherence to Novartis system and databases in order to maintain compliance.

· Keep abreast of newer updates in policy / guidelines related to regulatory, share updates with stakeholders, review impact and provide comments as needed, ensure timely response

· Assist RA Manager in regulatory intelligence, as assigned.

Minimum Requirements:

A degree in pharmacy, health discipline or life sciences (minimum)

A post-graduate degree in pharmacy, health discipline or life sciences (desirable).

Work Experience:

- · 6-7 y in relevant RA role commensurate with Indian regulatory scenario in Indian and multi-national companies
- · Experience of working cross-functionally - both local and with HQ/overseas

· Good communication skills

· Inter-personal skills

Appropriate IT literacy

- Cross Cultural Experience.
- Functional Breadth.
- Collaborating across boundaries.
- Operations Management and Execution.
- Project Management.

Skills:

- Documentation Management.
- Lifesciences.
- Operational Excellence.
- Regulatory Compliance.

Languages :

- 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

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部门
Development

Business Unit
Innovative Medicines

地点
India

站点
Mumbai (Head Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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Accessibility and accommodation

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