BR Submission Management, Specialist

Job ID
REQ-10022909

9月 19, 2024

India

摘要

Lead the BR cross-functional submission sub-teams ensuring that our regulatory dossiers are prepared in a timely manner and in compliance with Regulatory Authority regulations, guidance, SOPs, working practices and quality standards.

About the Role

- Manage activities associated with the preparation of Investigator Brochure (IB) annual updates within Biomedical Research (BR) in compliance with internal SOP and health authority requirements.
- Organizing and chairing the kick-off meeting to establish the level of update and contributors across Biomedical Research Translational Medicine and Development.
- Leads subsequent IB planning discussions, creating, and maintaining a comprehensive project plan, identifying key interdependencies/rate limiting steps, capturing actions and key activities, target governance board review, content delivery timelines, and finalization date for

IB, executing this plan according to agreed timelines.
- Manage stakeholder engagement, and ensure that any issues, risks, or impact due to changes in strategy and/or timelines are assessed quickly and remediated.
- Timely escalation (as per agreed process) if the IB will not be finalized within the annual update period.
- Collaboration with Document Quality Management (DQM) team and other key stakeholders e.g. Regulatory Operations, to ensure strategic resource planning of downstream activities allowing IB to be finalized in accordance with targeted timelines. Completion of all internal documentation and distribution of the final IB package in accordance with SOP and internal guidance.
- Timely update of all internal tracking systems.
- Manage submission related activities associated with the preparation of Clinical Trial Application/IND submissions following internal working practice, guidance, and SOPs to ensure the delivery of high-quality submission documents to regulatory operations.
- Including creation of requisite templates, drafting of timelines, ensuring documents are finalized according to internal process via source data verification and formatting checks in accordance with agreed timelines, in addition to the oversight of the preparation/delivery of supportive documentation and stakeholder management.
- May manage the preparation of Biomedical Research components (preclinical and early phase clinical) of supplementary submissions.
- May distribute workload to and collaborate with external vendor on documentation specific activities.
- Regularly maintain supporting IT systems/trackers to ensure accuracy of information by liaising with stakeholders.

QUALIFICTION & KEY COMPETENCIES

Education / Background:

Undergraduate degree, preferably in a scientific discipline or life science background or equivalent work experience

Years of Experience:

Minimum of 1-2 years ' experience working in a regulated, life science environment (pharmaceutical, biotechnology)

Key Competencies:

- Comprehensive understanding of relevant technical requirements for electronic registration submissions (eCTD) e.g. Bookmarking, hyperlinking, cross referencing etc.
- Demonstrated ability to work successfully within a matrix environment and influence cross functional teams.
- Experience with and ability to understand compliance practices which include GxPs and Standard Operating Procedures
- Proficient in Microsoft Office suite in addition to SharePoint.
- Strong oral and written communication skills and customer service skills and organizational skills.
- Self-starter with a proven ability to prioritize work, multitask, display customer centricity, and manage time appropriately, in a fast paced/high volume environment.

- Demonstrated organizational skills.

Languages:

Fluent oral and written English

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部门
Biomedical Research

地点
India

站点
Hyderabad (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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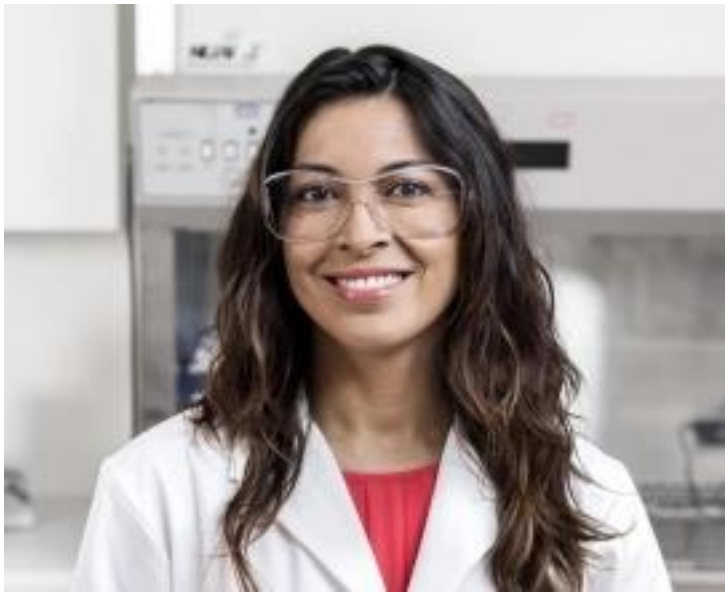

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