BR Submission Management, Lead

Job ID
REQ-10022904

9月 19, 2024

India

摘要

Lead the BR cross-functional submission sub-teams to project manage regulatory submissions ensuring that applications and dossiers are prepared in a timely manner and in compliance with Regulatory Authority regulations, guidance, Novartis SOPs, working practices and quality standards. Train and guide authors and contributors on regulatory submission requirements. Mentor/coach less experienced team members within BR Submission Management.

About the Role

- Manage the preparation of the BR submission components of regulatory submission dossiers such as IND, NDA, MAA (i.e., medium to high complexity submissions).
- Leads submission planning discussions, developing, and maintaining a comprehensive strategic submission plan including a detailed list of dossier content, interdependencies, key activities, target governance board review timeframes, content delivery timelines, and credible dispatch dates and executing this plan.

- Ensure the submission team are aligned of upcoming deliverables and roles and responsibilities and that they understand the interdependencies between submission activities and components, and that any issues, risks, or impact due to changes in strategy and/or timelines are assessed quickly and remediated, throughout the submission process.
- Utilizes strong knowledge of global regulatory submission requirements, processes and procedures, technical requirements, and planning software to ensure teams meet aggressive target submission dates, by proactively focusing on critical path analysis, hand-offs, and prospective scenarios (when multiple regulatory strategies are being considered), thus reducing "rework" to avoid costly time delays.
- Collaborate with Document Quality Management team and other key partners such as BR Quality to ensure strategic resource planning of downstream activities allowing deliverables to me finalized in accordance with targeted submission timelines.
- Performs the role of Investigator Brochure compiler for First-in-Human studies and subsequent annual updates in accordance with regulatory requirements and internal Novartis guidelines and SOPs.
- Provides various data visuals, to facilitate awareness of key milestones, closely monitors critical path activities, and ensures transparency of submission status to stakeholders.

- Provide strategic input relating to submission requirements for migration of submission related supportive documentation for in licensed/joint ventures and acquired assets. Managing the preparation of the subsequent dossier preparation therein.
- Mentor/coach less experienced Submission Management team members.
- May lead continuous improvement activities related to submission processes and regulatory document management within BR.
- Update assigned internal planning systems, to allow maximum transparency, thus ensuring strategic business decisions can be made for expeditious resource planning, both within Submission Management and cross-functionally within BR.
- Act as subject matter expert for submission related global cross-divisional strategic projects ensuring BR interests are represented.

Education / Background:
Undergraduate degree, preferably in a scientific discipline or life science background or equivalent work experience
Years of Experience:
3-5 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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Accessibility and accommodation

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