Biomedical Research Submission Management, Associate Director

Job ID
REQ-10037238

2月 18, 2025

Switzerland

摘要

More than 100,000 people across 140 countries are working for Novartis to discover, develop, and successfully market innovative products to prevent and cure diseases, ease suffering, and enhance the quality of life.

The Biomedical Research Submission Management, Associate Director will 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 and working practices and quality standards. They will also train and guide authors and contributors on regulatory submission requirements and have managerial responsibility for local submission manager team.

About the Role

Major accountabilities:

- Managerial responsibility for local submission management team.
- Manage the preparation of the BR submission components regulatory submission dossiers such as NDA, MAA (i.e., high complexity submissions).
- Leads submission planning discussions, developing, and maintaining a comprehensive strategic submission plan including a detailed list of dossier content, interdependence, key activities, target governance board review time frames, content delivery timelines, credible dispatch dates and executing this plan.
- 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.
- May act as deputy for Head BR Submission Management upon request.
- Leads continuous improvement activities related to submission processes and regulatory document management within BR.
- Contribute to the development of key performance indications for the submission management group.
- Maintain the group ' s knowledge of evolving submission requirements, ensuring BR is building strategies to proactively prepare the organization for the future.
- Participation in audits and inspections and execution of any resultant corrective action plans.
- May oversee maintenance of specialized expertise on current templates, processes, systems, electronic submission standards regulatory guidelines and legal requirements, as relevant to SM, and training of associates, submission management teams and vendors thereon.

Minimum Requirements:

- Undergraduate degree, preferably in a scientific discipline or life science background or equivalent work experience
- 5-10 years ' experience working in a regulated, life science environment (pharmaceutical, biotechnology), with 2-3 years ' experience as people manager.
- Project management experience in the pharmaceutical industry or in a regulatory environment.
- Expert knowledge of Regulatory Affairs responsibilities from pre-IND through Phases I-IV preferred.
- Demonstrated leadership and negotiation skills with ability to persuade and influence others (regardless of level) in achieving team and submission objectives.
- Ability to interpret regulations and gain consensus on a way forward in an environment where there may be more than one way of achieving a successful outcome.
- Effectively lead multidisciplinary team meetings and drive discussions regarding submission content, timelines, resource allocation, risk management, etc.
- Ability to proactively identify and mitigate risks and potential bottlenecks, apply sound judgement when determining if/when to escalate issues, and effectively interact with stake holders to ensure transparency of submission progress/status.

Why Novartis: Our purpose is to reimagine medicine to improve and extend people ' s lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-

and-culture

Commitment to Diversity and Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to all

individuals. If, because of a medical condition or disability, you need a reasonable

accommodation for any part of the recruitment process, or in order to receive more detailed

information about the essential functions of a position, please send an e-mail to diversity.inclusionch@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message

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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
Biomedical Research

Business Unit
Pharma Research

地点
Switzerland

站点
Basel (City)

Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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