Biomedical Research Submission Management, Associate Director

Job ID
REQ-10037240
Φεβ 18, 2025
USA

Περίληψη

#LI-Hybrid

About the role:

This position can be based in East Hanover, NJ or Cambridge, MA.

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

Key Responsibilities:

- 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.

Essential 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.

Commitment to Diversity and Inclusion / EEO: The Novartis Group of Companies are Equal Opportunity Employers and take pride in maintaining a diverse environment. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, gender, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash their full potential.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $132,300.00/year to $245,700/year; however, while salary ranges are effective from 1/1/25 through 12/31/25, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills, and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an "at-will position" and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status.

Accessibility & Reasonable Accommodations

The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 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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Pharma Research
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Κατάσταση
New Jersey
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Employment Type
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REQ-10037240

Biomedical Research Submission Management, Associate Director

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