NOVARTIS

Submission Manager " >

Job ID
317660BR
USA

Job Description

799 million. That’s how many lives our products touch. And while we’re proud of that fact, in this world of digital and technological transformation, we must also ask ourselves this: how can we continue to improve and extend even more people’s lives?
Job Purpose
Responsible for the planning, coordination, development and timely delivery of high quality Clinical submission documents to Regulatory Affairs (RA) for 1) New Drug Applications (NDA), Biologic Licensing Applications (BLA), Marketing Authorization Applications (MAA) and supplemental NDAs/BLAs/ Type II variations, 2) for related follow-up activities (e.g. Safety Updates, answers to Health Authority (HA) questions).
Major Accountabilities
1. Provide cross-divisional Preclinical and/or Clinical submission leadership and serve as content/technical specialist for Preclinical and/or Clinical submission document requirements for assigned programs supported by Submission Management Department.
2. Contribute to the global cross-functional Clinical Submission Team to ensure all Clinical submission documents are delivered in accordance with timelines, high quality, operational and technical procedures; report Clinical submission progress and issues with a resolution plan to Group Heads of Submission Management, Regulatory Affairs and other relevant line units Heads, as needed.
3. Contribute to the Clinical Submission Planning Meeting with cross functional team members to define Clinical submission content, data pooling strategies for summary documents (e.g. Summary of Clinical Efficacy (SCE) and Summary of Clinical Safety (SCS)) and identify full Clinical Submission Team composition; provide meeting agenda and meeting minutes.
4. Facilitate definition of delivery schedule and batch content for statistical outputs and medical writing strategy ensuring continuous receipt, review and integration into Summary Documents (e.g. SCE, SCS and Clinical Overview (CO)).
5. Contribute to the identification of all Clinical submission deliverables (including all relevant trials); negotiating and tracking timelines, accountabilities and responsible individuals assigned in collaboration with Clinical Submission Team members for HA filings; include on RA submission tracker and maintain with real-time updates.
6. Anticipate and identify issues and potential resource gaps effecting preparation and delivery of Preclinical and/or Clinical submission documents across line functions. Implement solutions.
7. Contribute to pre-submission Health Authority briefing books.
8. Co-Facilitate extended Clinical Submission Team meetings to synchronize submission messages with Senior Management at:
a. Clinical Submission Team Kick-off – goal is to ensure clear submission strategy and early target labeling messages endorsed by Senior Management and understood by all Preclinical and/or Clinical submission team members; all contributing line units present proactive assessment of key issues and actions within their lines which will effect timely delivery of Preclinical and/or Clinical submission documents. Agenda and meeting minutes issued by Submission Manager (SM).

b. Key Message Harmonization Meeting – goal is to ensure Senior Management and cross functional development departments are aligned on key efficacy, safety, Biopharmaceutics and Clinical Pharmacology messages following receipt of key pooled Clinical data. Agenda and meeting minutes issued by SM. Meeting co-facilitated with RA.

Diversity & 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.

Minimum Requirements

Education:
• Bachelor's degree or equivalent education/degree in life science/healthcare is required.
• ≥ 2 years' experience in Clinical research with proven proficiency in global Clinical development (preferred)
• Fundamental leadership of cross-functional teams. Has demonstrated teamwork, communication and organizational skills. Works effectively and is able to establish relationships with other line functions
• Strong working knowledge in world wide regulatory requirements for drug registration (e.g., Common Technical Document)
• Previous experience in medical writing, Preclinical and/or Clinical submissions, and interactions with health authorities is preferred
• Solid computer technical skills (Word / Excel / Power-point/MS Project) and ability to learn new systems quickly
Why consider Novartis?
We believe the answers are found when curious, courageous and collaborative people like you are brought together in an inspiring environment. Where you're given opportunities to explore the power of digital and data. Where you're empowered to risk failure by taking smart risks, and where you're surrounded by people who share your determination to tackle the world's toughest medical challenges.
Imagine what you could do at Novartis!
Division
Global Drug Development
Business Unit
GDO GDD
Location
USA
Site
East Hanover, NJ
Company / Legal Entity
Novartis Pharmaceuticals
Functional Area
Research & Development
Job Type
Full Time
Employment Type

Regular
Shift Work
No
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Job ID
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Submission Manager

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