TMF SWAT Manager

Job ID
REQ-10045337
Apr 29, 2025
United Kingdom

Summary

This is a unique opportunity to join Clinical Development Document and Governance Management team as a TMF SWAT Manager!

About the Role

This is a hybrid role and can be based in London, Dublin or Hyderabad offices. The expectation is to be in the office 12 days/month

Major accountabilities:

- Act as CDGM point of contact for assigned portfolio of In-Licensing / Out-Licensing / Acquisition / Divestment Projects, collaborating with key stakeholders with CDGM teams, Development Informatics, Legal, Development Quality Assurance and Global Project Teams.
- Lead and/or Contribute to the development of TMF Transition Plans and ensure the successful transitions of TMF (paper and electronic) documentation outside of Novartis in support of out-licensing and divestment projects, and into Novartis in support of in-licensing and acquisition projects.
- Develop and maintain paper and electronic document processes & standards relating to BD&L projects and Out licensing activities, in compliance with internal and external requirements & regulations
- Identify and communicate risks/trends/patterns relating to TMF, BD&L projects, Out licensing activities and work with key stakeholders to define and implement pragmatic remediations.
- Executes vendor oversight plan, monitors service metrics and identifies opportunities for improvement to the operating model. Acts as point of escalation for issues.
- Serves as Subject Matter Expert on TMF transition related training materials, formal and informal processes and tracking tools for TMF transition oversight activities in collaboration with CDM Process team and other key stakeholders
- Provides support for inspections/audits, contributes to root cause analysis identification and creation/delivery of CAPAs.
- Identify and implement improvements to document management processes to improve quality of TMF integration activities. May act as business lead for innovation projects to enhance integration processes.
- Supports the TMF Integration Lead with respect to forecasting and planning of B&&L projects.

Relevant Experience:

- Minimum of 5 years working in clinical research and development in the pharmaceutical industry (and/or Contract Research Organisations) with specific experience in clinical documentation and/or records & information management.
- Demonstrated success in planning and executing cross functional projects.

- Strong influencing and presentation skills. Ability to communicate effectively at all levels.
- High organisational awareness, including experience working in multi-disciplinary teams, across cultures and geographies.
- Good negotiation, problem solving and conflict resolution skills; experience establishing trusted relationships with internal and external stakeholders.

Languages :

- English.

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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.inclusion_ch@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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

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Division
Development
Business Unit
Universal Hierarchy Node
Location
United Kingdom
Site
London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Alternative Location 1
Dublin (NOCC), Ireland
Alternative Location 2
Hyderabad (Office), India
Functional Area
Research & Development

Job Type
Full time
Employment Type
Regular
Shift Work
No
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