TMF Integration Oversight Manager

Job ID
REQ-10054723

10月 31, 2025

USA

摘要

Title: TMF Integration Oversight Manager

The ideal location for this role is East Hanover, NJ but remote work may be possible (there may be some restrictions based on legal entity). Please note that this role would not provide relocation as a result. If associate is remote, all home office expenses and any travel/lodging to East Hanover, NJ site for periodic live meetings will be at the employee ' s expense. The expectation of working hours and travel (domestic and/or international) will be defined by the hiring manager. This position will require limited travel.

Clinical Document Governance Management (CDGM) is accountable for strategy and delivery of clinical document management (CDM) systems, processes, standards and operations of CDM services (including Trial Master File management (TMF), clinical submission readiness, record retention and archiving, Good Documentation Practice capability build) across Novartis globally. In addition, CDGM is driving the transformation of TMF at Novartis, through the introduction and adoption of new technologies, processes and ways of working.

The TMF Oversight Integration Manager ensure successful planning and transition of TMF documentation to and from Novartis in support of Mergers & Acquisition (M&A) projects and Out licensing activities. Drives implementation of CDGM initiatives, projects and process improvement activities to enhance clinical document management systems, processes and standards at Novartis.

#LI-Hybrid

Key Responsibilities:

Major accountabilities but not limited to:
- 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 M&A projects and Out licensing activities, in compliance with internal and external requirements & regulations.
- Identify and communicate risks/trends/patterns relating to TMF, M&A 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.
- Supports the TMF Integration Lead with respect to forecasting and planning of M&A projects.

About the Role

Requirements:

- Bachelor ' s degree or equivalent and relevant industry experience
- Minimum of 5 years working in clinical research and development in the pharmaceutical industry (and/or Contract Research Organizations) 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 organizational 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.
- Fluent in English

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $114,100/yr and $211,900/yr; ***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.

Company will not sponsor visas for this position.

Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

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

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.

部门
Development

Business Unit
Development

地点
USA

状态
Distant Working Arrangement, US

站点
Distant Employee - Distant Working Arrangement (DWA) (USA)

Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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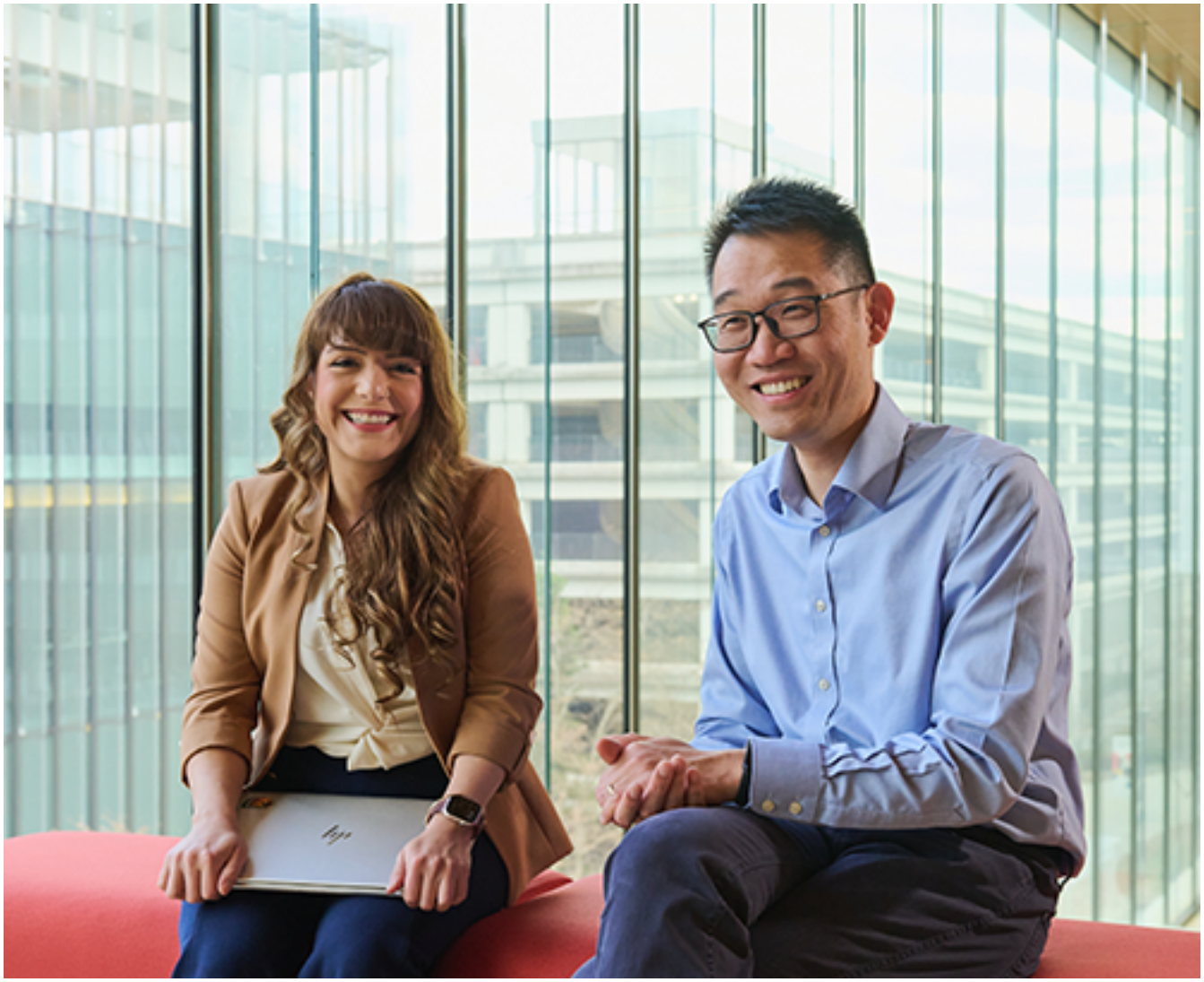

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