Clinical Document Migrations Manager

Job ID
REQ-10064709

12月 14, 2025

India

摘要

The Clinical Document Governance Management (CDGM) is responsible for the strategy and implementation of clinical document management (CDM) systems, processes, and standards; as well as the operations of CDM services, which include Trial Master File (TMF) management, clinical submission preparedness, record retention, TMF integrations for BD&L deal, archiving and enhancing Good Documentation Practice capability worldwide in Novartis. Additionally, CDGM spearheads the transformation of TMF at Novartis by pioneering the adoption of revolutionary technologies, processes, and working methods.
We are seeking a knowledgeable and experienced Clinical Document Management - Business Migrations Manager to handle the strategy, planning and delivery of technical migrations to, from, and within Novartis enterprise-wide clinical electronic document management systems. This role will be pivotal in implementing the Clinical Document Governance Management initiatives, projects, and process improvement activities.

About the Role

Responsibilities:

- Lead the implementation of CDGM initiatives to enhance the planning and execution of technical migrations.
- Liaise with internal and external stakeholders to plan and execute technical migrations, ensuring alignment with Novartis business, compliance, and operational requirements.
- Collaborate with stakeholders to identify and agree on migration business requirements, understand source and target system capabilities and develop a future technical migration roadmap.
- Serve as a Subject Matter Expert for training materials and tracking tools for eDMS technical migration activities.
- Manage activities related to migration-related Incident Management, Change Management, and ongoing operations of the eDMS.
- Support the forecasting of internal resource allocations and vendor-provided activities as part of eDMS migration roadmap management.
- Execute the vendor oversight plan, monitor service metrics, and identify opportunities for improvement.
- Provide support for inspections/audits, contribute to root cause analysis and creation/delivery of CAPAs.

Requirements:

- Advanced degree or a combination of Bachelor ' s degree in information or life sciences/healthcare and relevant industry experience.
- Minimum of 6 years working in Pharmaceuticals, Life sciences, and Clinical Research with specific experience in leading of clinical document management, TMF and/or records & information management technical migration.
- Minimum of 5 years of full-scale technical migrations of clinical documents, particularly eTMF.
- At least 2 major experiences in Veeva Vault related technical migrations.
- Prior experience and knowledge of Trial Master File (TMF) reference model.
- Prior experience in Electronic Document Management systems, specifically in Clinical and Regulatory (e.g. Veeva Clinical vault, RIM, Documentum D2LS)
- Deep knowledge of Agile working methodologies.
- Strong influencing and presentation skills. Ability to communicate effectively at all levels.

Desired Skills:

Clinical document management technical migration, Budget Management, Clinical Trials, Coaching, Data Analysis, Data Integrity, Learning Design, Life sciences, Risk Monitoring, Trends Analysis, Veeva Vault, TMF.

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Development

Business Unit
Development

地点
India

站点
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Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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