Clinical Document Management - Business Migrations Manager

Job ID
365482BR
Ott 02, 2024
Irlanda

Sommario

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.

About the Role

The CDM Business Migrations Manager is responsible for effective planning and delivery of migrations to and from of Novartis enterprise-wide clinical electronic document management systems (eDMS) aligned to Novartis business needs, partnering with technical vendors, internal IT and business stakeholders.

- Drives implementation of CDGM initiatives, projects and process improvement activities to enhance the planning and execution of migrations to and from enterprise clinical eDMS at Novartis.
- Act as CDGM point of contact for partnering with CDGM, IT (internal and external) and business stakeholders to plan and execute migrations to and from eDMS, in line with Novartis business, compliance and operational requirements.
- Partner with CDGM and business stakeholders, especially those planning in-licensing and out-licensing activities to identify and agree migration business requirements, understand source and target system capabilities and develop/maintain a future migration roadmap.
- Contribute to activities to ensure efficient processes & integrations of systems with eDMS based on strong understanding of Novartis enterprise systems landscape and in line with compliance and business priorities. Serves as Subject Matter Expert for training materials, formal and informal processes and tracking tools for eDMS migration activities, in collaboration with CDM Process team and other key stakeholders
- Plan and contribute to agile working methodologies being applied during development cycles to prepare for migration and during post migration hyper care period.
- Owner or Contributor of activities related to migration related Incident Management, Change Management and ongoing operations of the eDMS.
- Support forecasting of internal resource allocations and vendor provided activities as part of eDMS migration roadmap management.
- Executes vendor oversight plan, monitors service metrics and identifies opportunities for improvement to the operating model in relation to migration. Acts as point of escalation for issues.

- Provides support for inspections/audits, contributes to root cause analysis identification and creation/delivery of CAPAs.

Minimum Requirements:

- Advanced degree or combination of Bachelor's degree in information or life-sciences/healthcare and relevant industry experience. Minimum of 6 years working in Pharmaceuticals, Lifesciences and Clinical Research with specific experience in contributing and leading of clinical document management, TMF and/or records & information management.
- Minimum of 5 years of full-scale migrations
- Minimum 2 medium to major Veeva related hands-on and provable experience in leading and planning of migrations.
- Prior experience in Electronic Document Management systems, specifically in Clinical and Regulatory highly desired.
- Business relevant technical and working experience of eDMS systems like Veeva Clinical vault, RIM, Documentum D2LS or similar
- Knowledge of industrywide Electronic and Clinical Document Management systems and features
- Deep knowledge of Agile way of working with cross functional teams for releases
- Strong influencing and presentation skills. Ability to communicate effectively at all levels

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Business Unit
Innovative Medicines
Posizione
Irlanda
Sito
Dublin (NOCC)
Company / Legal Entity
IE02 (FCRS = IE002) Novartis Ireland Ltd
Alternative Location 1
Hyderabad (Office), India
Functional Area
Research & Development

Job Type
Full time
Employment Type
Regular
Shift Work
No
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