Manager, Systems Management

Job ID
REQ-10045252

4月 03, 2025

India

摘要

Applies scientific and computing skills with the knowledge of the business environment to maintain drug safety related systems and to develop sustaining solutions to meet the evolving needs in the area of Pharmacovigilance and Clinical Safety. Translates requirements and enable creation of value-added IT solutions with the evolving regulations in mind. Supports improvement of PS&PV business processes through implementation of appropriate IT methods, its configurations following change control processes for advanced technical changes to support the business users of PS&PV on daily business and while audits/inspections. Responsible for working with internal and external partners, to implement x- functional processes, technologies, solutions and services, supporting innovation in evidence-based decision making and insight generation to continuously improve PS&PV organizational performance.

About the Role

Major accountabilities:

- With the support of Asso. Director. Systems Management facilitate discussions to help Global Development to anticipate future needs and opportunities and communicate where technology can help.
- Work with Systems Management colleagues to raise new project proposals and mandates and support definition of the business case, conduct assessments of processes and detail requirements
- Collaborate with project teams to determine scope, goals and objectives
- Guide the Business lead to definite business value and associated metrics
- Interview business partners, organize and run requirements sessions with groups of users.
- Analyse and model relevant business processes, rules and data and relationships by documenting the "as is" process and provide guidance to the business analyst to create the "to be" process
- Determine data flows and sources; prepare data conversion or migration needed to support goals and uses in a process.
- Collaborate with project team to define solutions that deliver business value.
- Contribute to outlining performance qualification testing and validation plans.
- Analyze, Understand, Collect, Test, Implement, and Maintain safety database configuration changes functions from Global Development and External line functions. An understanding of functional area and IT domain is required.
- Perform QC check on configuration changes, identify discrepancies between the request and the implementation and resolve or initiate their resolution.
- Understand Global Development processes to support and lead process improvement initiatives.
- Perform the role of first line operational support for safety database users and provide system administration support for Global Development applications as appropriate
- Develop; provide support to create complex specialized reports from PS&PV systems as appropriate.
- Coach, train and mentor new Experts Systems management as appropriate and bring them to the next level.
- Facilitate audit and inspection preparedness, and lead discussions with auditors and inspectors.
- Assume full responsibility for routine operations and projects, whether as an individual contributor, team leader, or system owner.
- Ensure system traceability and adhere to proper documentation practices to manage and maintain technical and procedural artifacts.
- Collaborate effectively with external service providers and support governance and performance activities.

Minimum Requirements:
Work Experience:

- Collaborating across boundaries.
- Project Management.
- At least 7 years' experience in drug development in the area of safety database administration and support.
- At least 4 years in the discipline of safety data management.
- Experience with ORACLE, SAS databases.
- High level of competence with SQL.

- Thorough understanding of MedDRA, Disease dictionaries
- Broad and in-depth knowledge of Drug safety business processes.
- Thorough understanding of the issues aligning IT solutions with business needs.
- Excellent mentoring and coaching skills
- Ability to form, lead, and deliver initiatives

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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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