

Non Drug Program Associate Director

Job ID

REQ-10030225

Nov 17, 2024

India

About the Role

Major accountabilities:

- Leads Data Mgmt activities for high priority/complex programs/projects -May act as local manager of global associates including providing supervision and advise to these data managers on functional expertise and processes -Accountable for all aspects of the Process and Training department to ensure full compliance to all applicable global regulatory requirements is maintained and business objectives are achieved.
- Drive functional excellence by contributing to the definition of the strategic goals and operating policies, and leading/contributing to strategic initiatives in line with the overall strategy.
- May define SLA and negotiate with partners to establish optimal Statements of Work.
- Lead the development, collection, coordination and implementation of metrics for for both internal associates and external (CRO, FSP) resources and activities.
- Represents and drives Quality and Compliance organization -Manages and measures organizational quality.
- Ensures appropriate exceptions requests, deviations and CAPA plans.
- Build and maintain effective working relationship with cross -Representative at project-level and in the Submission team, or in local leadership team.
- Ensures compliance with company, department and industry standards/processes, -Oversees and is responsible for quality control and audit readiness of all assigned data Mgmt deliverables as well as accuracy and reliability of data within databases of assigned project(s).
- Maintain up-to-date advanced knowledge of industry software and reporting tools as well as industry requirements -Represent Data Mgmt at audits and in Health Authority (HA) meetings for assigned project(s), or on data amangement aspects in external conferences or groups -Mentors others to develop their own leadership capabilities and identifies/develops talent -Selects, recruits, develops, manages, motivates, coaches, develops talent and appraises the performance of direct reports to ensure high quality performance across his/her Clinical Data Mgmt Group -Leads and supports clinical and non - clinical special projects and initiatives -Propose creation of new SOPs, NIPs and WPs where appropriate, provide input to undertake implementation and maintenance of such documents , standards.
- Provide necessary help and support to address and resolve issues, Identifies solutions for remediation.
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Key performance indicators:

- Achieve high level of quality, timeliness, cost efficiency and customer satisfaction across Data Mgmt activities and deliverables.

- No critical audit findings due to Data Mgmt -Effectiveness of participation in internal and external networks/initiatives.
- Effectiveness of recruitment, retention and development of talent.
- Efficiency of resource usage.
- Adequacy of resource estimation.
- Adherence to Novartis policy and guidelines -Customer / partner/ project feedback and satisfaction

Minimum Requirements:

Work Experience:

- Cross Cultural Experience.
- People Leadership.
- Project Management.

Skills:

- Clinical Data Management.
- Cross-Functional Team.
- Data Architecture.
- Data Governance.
- Data Management.
- Data Quality.
- Data Science.
- Data Strategy.
- Drug Development.
- Master Data.
- People Management.
- Project Management.

Languages :

- English.

Role Requirements

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

Innovative Medicines

Location

India

Site

Hyderabad (Office)

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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