Associate Director Data Ops & Analytics, RDQ

Job ID
REQ-10017456
Aug 06, 2024
India

Summary

As Research & Development Quality (RDQ) representative, support the Research & Development key business processes related to Database Development, Data Management, Statistical Programming and Analytics by providing expertise and guidance to ensure that clinical data flow, management & analysis processes are fit for purpose and meet Novartis standards, Health Authorities regulations and GCP guidelines. Engage with Research & Development business and quality teams to identify potential quality risks and provide guidance to business on the control and mitigation measures.

About the Role

Associate Director Data Operations & Analytics RDQ

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As Research and Development Quality (RDQ) representative, support the Development key business processes related to Database Development, Data Management, Statistical Programming and Analytics by providing expertise and guidance to ensure that clinical data flow, management & analysis processes are fit for purpose and meet Novartis standards, Health Authorities regulations and GCP guidelines. Engage with Development business and quality teams to identify potential quality risks and provide guidance to business on the control and mitigation measures.

Key Responsibilities:

- Provide quality advice and oversight to ensure required standards and regulations are followed during end-to-end data flow and data analysis processes (e.g. development of study into electronic data capture systems, study build/ conduct/ close out, statistical analysis and clinical study report development).
- Support relevant Business functions during audit/inspections preparation, response to requests and CAPA creation.
- Partner across business units/ divisions to support programs to embed and implement digital capabilities, data science and new technology into the drug development and the end-to-end clinical trial processes in scope.
- Be an ambassador for the Novartis values and behaviors.
- Collaborate with different functions (e.g. Business Franchises, Global Data Operations Organization, Pharmacovigilance, Clinical, CDE&A, IT, and other teams) to contribute in development of suitable business strategies resulting in a capable, experienced and empowered Database Development, Data Management, Statistical Programming and Analytics organization. Ensure information flow and alignment with internal and external partners/ stakeholders.
- Support business units to ensure relevant quality documents (guidelines, SOPs, Quality Standards, etc.)

are fit for purpose and meet Novartis standards, Health Authorities regulations and GCP guidelines for existing and new processes & technologies.
- Support Development and RDQ teams to ensure new processes and technologies are risk-assessed and understood.
- Provide consultancy on Integration and Due Diligence activities linked to Business Development and Licensing (BD&L) for in scope Business Process and relevant Business Functions.
- Proactively identify regulatory, quality and compliance risks for assigned areas/ activities/ projects and support Business to establish mechanisms to mitigate these risks. Ensure Clinical Trial Quality Risk Management concepts are applied as applicable
- Provide expertise and guidance to business partners in investigations, root cause analysis and risk mitigation assessments of quality incidents as per and change management process.
- Contribute in cross-functional projects/ workstreams to continuously improve Novartis standards, processes and systems to ensure better process adherence and to simplify the way we work. Provide comments to relevant regulations during consultation period as requested.
- Foster a culture of collaboration and capability building by delivering educational and learning preparations (e.g. training, lessons learned and successes sharing, regular meetings with internal and external partners/ stakeholders).
- Support other assigned tasks as required within GI. GDD Quality Data & Digital Processes scope and deputize for peers and manager as needed.

Essential Requirements:

- Significant relevant work experience (> 10 years) in the pharmaceutical industry or public health sector, in the area of Quality, Information Technology, Data & Digital and/or Clinical Development.
- Strong background and experience in GCP, PV and other relevant Health Authority regulations, paired with good business understanding. Understanding of CSV and Part 11 requirements as well as privacy and information security regulations.
- Exemplary interpersonal skills demonstrating the Novartis values for collaboration, quality and integrity; ability to bridge between quality, scientific and business experts.
- Flexibility in problem solving and providing direction to meet business needs objectives.
- Ability to innovative when faced with opportunities or challenges.
- High learning agility, comfortable with complexity and diversity, and highly interested in continuous improvement.
- Excellence in communicating effectively across different audiences and organizational levels.
- High awareness of trends and ability to proactively address needs based on external demands.
- Proven ability to build strong and effective relationships with internal and external partners.
- Change management skills to facilitate changes and sustain a culture of high ethical standards and compliance.

Desirable Requirements:

- Bachelor’s degree in Life Sciences, Statistics, Information Technology or related fields. Master’s degree or equivalent is a plus.

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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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Site
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IN10 (FCRS = IN010) Novartis Healthcare Private Limited
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Quality
Job Type
Full time
Employment Type
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Shift Work
No
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