Director Statistical Programming

Job ID
REQ-10040551
Feb 17, 2025
India

Summary

Provides expertise under the Global Head, Statistical Programming in AQS Development, focusing on quality, CDISC standards, open-source capabilities, automation, and data structures for modeling. This role requires extensive experience in drug development, GCP, and regulatory requirements.
Enhances open-source programming capabilities and programming/ reporting standards across therapeutic areas. Acts as an influential leader, representing Statistical Programming at leadership meetings, overseeing and coordinating all functional activities. Collaborates to ensure consistency in programming practices across sub-functions. Leads initiatives to establish AQS as industry best-in-class.

About the Role

Major accountabilities:

- Drives productivity and efficiency measures to meet the strategic imperatives within AQS sub-functions, quality and productivity targets. Actively ensures that team's performance measures are being met or exceeded. Takes appropriate action when needed to drive corrective measures.
- Establish and maintain a high performing Organization: (i) Mentor leadership talent and high performing associates, (ii) Responsible for performance management/feedback, professional development, and training, (iii) Establish and steer a business founded on disease area knowledge, innovation, collaboration, quality, and trust.
- Evaluate Statistical Programming requirements of computer systems and needs that relate to programming and reporting activities that foster use of emerging technologies in an innovative but compliant manner.
- As a functional leader of AQS, acting with an enterprise mindset, is fully involved in all aspects of Statistical Programming including the development of future strategies and processes. Contributes to the further development of the AQS organization with a focus on continuous improvement and quality by fostering statistical programming innovations, processes and solutions that ensure efficient implementation and knowledge sharing across Novartis.
- Understands the needs and expectations of the different Health Authorities, ensures audit readiness and participates in Health Authority inspections. Monitors all assigned projects within DU/sub-function which includes BR/GMA, complying with Novartis, AQS and industry standards (e.g. CDISC) and processes.
- Builds and establishes a strong team based on technical agility, capability, quality focus, excellence in performance and Novartis values and behaviors. Ensures the team addresses compliance matters in a timely way.
- Identify the need for enhanced capability programs (R programming, Disease Area skills etc.) and support the establishment of technical, business, and soft skills for all Statistical Programming associates.
- Leads and supports global clinical and non-clinical projects and initiatives to drive functional excellence

within AQS,
- Ensures high quality communication and information flow on status of all deliverables to stakeholders, mitigates and manages risks

Key performance indicators:

- Achieve overall goals including quality and compliance to programming / reporting standards as set each year by AQS Leadership Team
- No critical inspection/audit findings attributed to Statistical Programming

Minimum Requirements:

University or college degree in life science, computer science, statistics or other relevant field.

Proven leadership, collaboration and organizational skills with demonstrated ability to successfully manage simultaneous deliverables and meet deadlines

Excellent understanding of clinical trial methodology, GCP and medical terminology

Languages:

- Fluent English (oral and written).

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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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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