Head Clinical Development Business Solutions

Job ID
REQ-10025728
Dez. 18, 2024
USA

Zusammenfassung

Onsite
Location: East Hanover, New Jersey
Hybrid
#LI-Hybrid

About the role:
We have an opportunity for a Head, Clinical Development Business Solutions. In this role, you will work closely with the Global Head Clinical Development Program Scientific Excellence as well as the Global Head Clinical Development to drive functional excellence and execution for the clinical development function. You will lead development and execution of the clinical development operational strategy to ensure clinical development process excellence and compliance, which includes functional oversight and strategic direction of all clinical development-owned processes, tools & systems, quality & compliance to regulations, and inspection-readiness. You will have an opportunity to partner with key stakeholders across the function and organization.

About the Role

Your Key Responsibilities:

- Assumes oversight of all Clinical Development-owned processes (e.g., Clinical Development Plan, Study Protocol, Clinical Data Review, Medical Devices in Clinical Trials, Investigators Brochure, Data Monitoring Committee, Steering Committee, and others) and their related systems, tools, templates, guidance documents, and standard operating procedures.
- Leads the Business Solutions team of Clinical Development process owners, by providing day-to-day guidance, talent management, career development, and succession planning activities. Attracts, develops, coaches, motivates, and retains top talent, building a leadership and skills pipeline for the future.
- Builds, promotes, and maintains partnerships with Global Clinical Operations, Advanced Quantitative Science, Quality, and other key Novartis divisional stakeholders. Ensures collaboration on key initiatives and defines proactive cross-functional operational plans to mitigate/manage operational and inspection risks
- Oversees the cross-functional deployment of Risk-Based Quality Management for Clinical Development and partner functions.
- Accountable for ensuring clinical trial teams are trained on Clinical Development-owned processes, guided in day-to-day activities, and supported during inspections and audits. Functional Process Owner, reporting to the Head of Business Solutions, is responsible for presenting and defending the end-to-end process to Health Authorities and inspectors.

- Ensures constant improvement of Clinical Development processes based on performance metrics and corrective actions, utilizing new technologies and insights from cross-industry forums (e.g., Transcelerate).
- Ensures that Clinical Development processes adhere to regulations (e.g., ICH guidelines, HA guidelines/regulations, ISO, etc.) and oversees quality and compliance in Clinical Development. This includes tracking process deviations, completing CAPAs, assigning GxP training, and addressing identified risks and gaps.

Video Link https://www.youtube.com/watch?v=ggbnzRY9z8w

Role Requirements:
Essential Requirements

- PhD or equivalent advanced degree in a scientific or healthcare relevant field with 10+ years pharma industry experience.
- Advanced knowledge of Clinical Development grounded on hands-on experience in phase 2/3 clinical trials.
- Strong leadership presence with the ability to present and interact with senior management.
- Strong evidence of strategic thinking, problem solving capabilities, scenario evaluation, contingency planning and operational effectiveness/innovation, especially in drug development.
- Deep understanding of GCP and regulatory standards and policies.
- Strong project management skills, able to adjust to multiple demands, shifting priorities and unexpected events while maintaining a positive work attitude.
- Proven track record in working across a matrix organization and demonstrating expert skills in building partnerships and negotiating agreements; Excel at collaboration.

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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The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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2. https://www.novartis.com/about/strategy/people-and-culture
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