Director, Evidence Generation & Compliance

Job ID
REQ-10056627

7月 03, 2025

USA

摘要

#LI-Hybrid

Novartis has an incredible opportunity for a talented individual to join our team as a Director Evidence Generation & Compliance. You will, be responsible for leading the safety and medical compliance function within the US Medical Affairs organization. Be responsible for direct and/or indirect management of people, as well as resource and budget management responsibility for their programs. Strategically partners with internal and external stakeholders to provide a center of excellence for Safety Risk Management and Medical Compliance across USMA.

This position is based is East Hanover, NJ and will not have the ability to be located remotely. Please note that this role would not provide relocation and only local candidates will be considered. The expectation of working hours and travel (domestic and/or international) will be defined by the hiring manager. This position will require up to 25% travel.

About the Role

Key Responsibilities:

- Leads Medical Quality and Compliance within the department.
- May serve as delegate for the ED/Head, Evidence Generation Excellence as requested.
- Collaborates and aligns with colleagues on activities pertaining to the annual IRO monitoring and annual ERC monitoring of medical activities and annual risk assessment.
- Collaborates with legal and ERC business partners as business needs dictate.
- Oversees investigations and ensures team is reporting deviations and events, including driving corrective action plans.
- Oversee appropriate follow-up and full execution/implementation and deviation management in appropriate system.
- Accountable for audits conducted within the organization.
- Serves as the safety risk expert on project/product teams throughout the product life cycle and contributes to the development and implementation of innovative policies and procedures that will ensure optimized compliance with minimized risk.
- Provides guidance to USMA on Patient Safety processes and requirements.
- Ensures USMA compliance with Pharmacovigilance (PV) Standard Operating Procedures and Working Practices
- Partners with the GDD risk management team and overall Patient Safety organization to work collaboratively towards addressing evolving needs and provide innovative solutions to balance the PV requirements of the Patient Safety organization with the business needs of USMA.
- Strategically partners with Global Patient Safety, RA, US Medical and Global development, and other functions to ensure that Global and US Risk Management strategies are aligned.
- Represent USMA requirements for any Patient Safety system enhancements
- Takes the lead on any Patient Safety related compliance activities (e.g., audits and remediation).
- Partners with medical, contracts and Patient Safety organization to resolve questions and requests for changes in template safety reporting language from institutions.
- Serves as the US MAP Medical Governance Lead (MGL) as single point of contact interacting with MAP governance representing US voice, suggesting process and system improvements, and reporting back to US key messages.
- Collaborates with key MAP stakeholders to ensure process alignment, assists in audits, metrics, and maintains oversight of US MAP program.
- Partners with clinical team and other line functions to ensure successful implementation of MAP programs from onset until product launch
- Serve as the MAP data steward by partnering with the clinical team to ensure system data is accurate and updated in a timely manner
- Ensures cross collaboration with other team members to develop reports and metrics for monitoring medical activities for compliance, including development and implementation of risk management plans.
- Oversees monitoring on predefined areas of business risk or ensure business conducts monitoring of its own business activities.
- Proactively identifies potential gaps or risk areas related to quality and compliance regulations, guidelines, and trends affecting Novartis, and supports implementation of improvement initiatives.
- Lead innovative solutions and communications that enhance compliance awareness across the organization.

Essential Requirements:

- Minimum of 7 years in drug development in a major pharmaceutical company including 5 years in safety at an operational or medical position preferred.
- Experience in clinical trial management, drug development, regulatory requirements, scientific methodology and/or broad understanding of Medical Affairs business functions required.
- Clear understanding of GCP regulations and knowledge of international and FDA regulations, PhRMA code and other industry guidelines and regulations.
- Strong leadership, project management, communication, presentation, and interpersonal skills required.
- Proven organizational skills with demonstrated expertise in influencing across a matrix and in managing multiple priorities.
- Ability to communicate effectively, manage issues, resolve conflicts, and mitigate risks
- Experience in preparation of clinical safety assessments and regulatory reports/submissions involving safety information.

Desirable Requirements:

- Experience of REMS/RMPs preferred.

Novartis Compensation Summary:

The salary for this position is expected to range between $168,000 and $312,000 per year.

The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors.

Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards.

US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we ' ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status.

Accessibility & Reasonable Accommodations

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.

部门
US

Business Unit
Universal Hierarchy Node

地点
USA

状态

New Jersey

站点
East Hanover

Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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