NOVARTIS

Head, US Pharmacovigilance Operational Excellence

Job ID
REQ-10059366

8月 18, 2025

USA

摘要

The Head of US Pharmacovigilance Operational Excellence is a leader responsible for driving strategic initiatives, innovation, and process transformation across the pharmacovigilance (PV) function. This role leads project management efforts and builds operational excellence capabilities to optimize efficiency, ensure quality, and maintain regulatory compliance. The role also oversees training, inspection readiness, and continuous improvement, fostering a culture of excellence and high performance. This role will also be leveraging benchmarking, competitive intelligence, business insights, and data-driven analyses to shape and execute strategies that drive competitive advantage and outcomes.

About the Role

#LI-Hybrid

Key Responsibilities:

Project Management & Change Leadership

- Lead and oversee a portfolio of high-impact pharmacovigilance (PV)/projects, ensuring timely delivery, stakeholder engagement, and *measurable outcomes*; spanning compliance, technology, systems implementation, organizational readiness, and process improvement
- Drive change management to support adoption of new tools, systems, and evolving compliance standards utilizing Lean, Six Sigma, and Agile methodologies to enhance quality and efficiency.
- Participate in global and cross-functional projects and meetings to ensure alignment and collaboration.

Operational Excellence, Process Development & Continuous Improvement

- Establish operational governance through the development and oversight of key performance indicators (KPIs)/metrics, leveraging dashboards & tools to monitor effectiveness, review trends monthly, identify and address performance gaps, and ensure accountability and alignment with business objectives to foster a performance-driven culture
- Lead the development, review, and ongoing enhancement of pharmacovigilance (PV) processes by simplifying and streamlining workflows through technology-driven solutions and implementing optimization opportunities
- Coordinate resource planning and budget management to ensure optimal allocation, cost-effectiveness, and support for strategic priorities

Compliance, Training & Inspection Readiness

- Lead investigations, root cause analyses, and CAPA development, identifying trends and systemic gaps, risk assessments, and quality improvement initiatives
- Design and manage a robust training framework that includes onboarding and continuous education to upskill teams, while ensuring compliance through accurate recordkeeping, regular monitoring, and periodic effectiveness assessments
- Drive audit and inspection readiness by managing logistics and execution, including mock audits, SME preparation, and development of inspection materials (e.g., opening presentations)

Strategic Advisory & Facilitation

- Develop and drive strategic roadmaps by identifying gaps and defining actions needed to optimize decision-making and ensure long-term success.
- Serve as a trusted advisor to senior leadership, participate in cross-functional meetings, offering expert guidance on strategy, regulatory compliance, and operational efficiency
- Act as a liaison among PV teams, regulatory authorities, and internal stakeholders to ensure alignment with best practices and regulatory expectations.

Essential Requirements:

- Advanced degree in life sciences, pharmacy, medicine, or related field (PharmD, MD, PhD, or equivalent)
- Minimum 8-10 years of relevant pharmacovigilance experience in the pharmaceutical, biotech, or CRO industry including medicinal, medical device, drug-device combination products or advanced therapies
- At least 3 years of demonstrated leadership in pharmacovigilance, including areas such as strategy, case management, PV compliance, inspection management, process development, and training, preferably in a matrixed or global environment within a multinational pharma company
- Proven expertise in project and program management, including PMO responsibilities
- Excellent organizational, analytical, and strategic planning skills, with strong attention to detail and a proven ability to resolve discrepancies and solve complex problems
- Exceptional interpersonal, communication, and stakeholder engagement skills, with the ability to influence at senior levels and foster a culture of innovation, collaboration, and accountability.
- Strong change management capabilities with the ability to influence and guide cross-functional teams through transformation.
- Strong knowledge of FDA, EMA, and ICH GVP regulations and industry best practices.

Desirable Experience

- Strong knowledge of methodologies such as PMP, PgMP, Agile, Lean, or Six Sigma; preferred certifications include Project Management Professional (PMP) and Certified Manager of Quality/Organizational Excellence (CMQ/OE)
- Proficiency in safety databases (e.g., Argus, Veeva Vault) and digital tools (e.g., Power BI, Power Automate), leveraging automation and analytics tools to enhance efficiency and generate actionable insights

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
Development

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

Apply to Job

Job ID
REQ-10059366

Head, US Pharmacovigilance Operational Excellence

Apply to Job

Source URL:
https://www.novartis.com.cn/careers/career-search/job/details/req-10059366-head-us-pharmacovigilance-operational-excellence

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. mailto:us.reasonableaccommodations@novartis.com
5. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/East-Hanover/Head--US-Pharmacovigilance-Operational-ExcellenceREQ-10059366
6. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/East-Hanover/Head--US-Pharmacovigilance-Operational-ExcellenceREQ-10059366