NOVARTIS

Head of US Patient Safety Pharmacovigilance Case Management

Job ID
REQ-10079595
Июн. 03, 2026
США

Сводка

#LI-Hybrid
Location: East Hanover, United States
Relocation Support: This role is based in East Hanover, United States. Novartis is unable to offer relocation support: please only apply if accessible.

Ready to lead at the forefront of patient safety and pharmacovigilance? As Head of US PS PV Case Management, you will shape how critical safety information is captured, processed, and delivered ensuring patients remain at the center of everything we do. This is a high-impact leadership role where you will drive end-to-end case management excellence, champion digital and artificial intelligence-enabled transformation, and build high-performing teams that deliver quality, compliance, and innovation at scale. You'll play a pivotal role in safeguarding patients while transforming the future of pharmacovigilance operations in a dynamic, globally connected environment.

About the Role

Key Responsibilities:

Strategic & Operational Leadership

- Lead end-to-end case management operations, including case intake, triage, processing, follow-up, quality control, case corrections and submission ensuring timely, accurate, and compliant safety reporting.
- Serve as the primary operational escalation point for complex, sensitive, or high-risk case processing issues and case-related risks and operational challenges.
- Ensure compliance with FDA regulations, ICH standards, and internal requirements.

Vendor Oversight & Quality Assurance

- Oversee vendor performance, governance, and capacity models to optimize delivery and resource mix.
- Maintain robust workload forecasting and capacity models; optimize in-house vs. vendor mix, responsible for resourcing.
- Drive quality, compliance, and performance through key performance indicators, audits, and inspection readiness initiatives.

Digitalization, AI & Process Excellence

- Champion digital, automation, and artificial intelligence solutions to enhance efficiency and data quality
- Identify and drive continuous process improvement initiatives, applying Lean and data-driven methodologies to simplify, standardize, and harmonize case handling processes.

People Leadership & Capability Development

- Build, coach, and develop high-performing teams, fostering a culture of continuous improvement and accountability.
- Foster a culture of quality, compliance, accountability, continuous improvement, inspection readiness and learning.

Global Coordination & Cross-Functional Engagement

- Serve as a key partner across internal and external stakeholders on adverse event reporting and case management, proactively identifying and mitigating issues to ensure aligned, effective, and compliant processes.
- Coordinate with Global Countries and Regions for simplified/harmonized practices and case exchange and collaborate with Regulatory Affairs, Quality, Legal/Data Privacy, Risk Management, and Medical Safety to support submissions, inspections, signal detection, RMPs, REMS, labeling updates, and periodic reports.

Essential Requirements:

- Bachelor's degree in a relevant life sciences or healthcare-related field. An advanced degree is preferred (Pharm. D., M.D., Ph.D.).
- 10+ years pharmacovigilance experience with 7+ years leading case management teams and vendors in medium-to-large pharma/biotech, including regulatory submissions.
- Strong knowledge of FDA PV regulations and ICH E2A/E2D/E2B(R3); deep understanding of MedDRA coding and case medical evaluation.
- Hands-on strong expertise with safety databases (Argus, Veeva Vault Safety, or similar), E2B(R3) case exchange, Electronic Data Capture (EDC) systems, call center telephony systems, and quality systems.
- Experience with drug, biologics, medical devices and combination products.
- Experience with project management and process excellence methodologies (e.g., Lean, Six Sigma).
- Strong leadership capability, with a track record of developing high-performing teams and driving operational excellence.
- Demonstrated capability to influence, provide strategic direction, negotiate, and resolve complex regulatory and operational challenges.
- Demonstrated experience leading inspections, audits, and ensuring inspection readiness.
- Proven people leadership experience, including coaching and developing managers and teams.
- Excellent planning, communication, interpersonal, and organizational skills, with a demonstrated ability to think innovatively and strategically at an enterprise level.
- Ability to lead cross-functional teams and deliver complex transformation initiatives, including digital automation and artificial intelligence solutions.
- Experience with patient support program data flows and third-party oversight.
- Expertise in workflow design, resourcing, budgeting, and performance monitoring.

The salary for this position is expected to range between $204,000 and $379,000 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.

To learn more about the culture, rewards and benefits we offer our peopleclick here.

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

Benefits and Rewards:

Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

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.

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Employment Type
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