NOVARTIS

Head of US Risk Management & Product Safety (REMS)

Job ID
REQ-10076170

4月 30, 2026

USA

摘要

Location: East Hanover, NJ

#LI-Hybrid

Relocation Support: Novartis is unable to offer relocation support - please only apply if this location is accessible to you

This Director level role will lead the US safety strategy behind some of Novartis ’ most complex and high-impact medicines. As Head of US Risk Management & Product Safety, you ’ ll own the end-to-end design and execution of Risk Evaluation and Mitigation Strategies (REMS) and leading product safety activities, shaping how patients safely access innovative therapies across the United States.

In this influential role, you ’ ll partner closely with FDA and senior cross-functional leaders, drive inspection-ready operations, and translate evolving regulatory expectations into practical, patient-centric risk management that enables confident, compliant commercialization.

About the Role

Major accountabilities:

1. REMS Strategy & Leadership

- Lead the US REMS Safety Strategy, ensuring alignment with FDA requirements, global risk management plans, and evolving patient safety priorities.

- Drive development, approval, and launch of innovative, commercially feasible REMS programs including restricted distribution, prescriber/pharmacy certification, and patient enrollment systems.

- Provide US input into Risk Management Plans (RMPs) and REMS assessments; ensuring the implementation of recommendations and continuous optimization of risk minimization measures.

2. REMS Operational Oversight

- Manage REMS vendor performance (including call centers, specialty pharmacies, prescriber certification platforms) to ensure compliance, high quality training, and robust data integrity.

- Oversee execution of REMS commitments and risk mitigation activities.

3. US Product Safety Strategy

- Oversee US safety related labeling (USPI, Medication Guides, REMS safety language) and oversee timely, accurate submission of US aggregate reports (e.g., PADERs, PBRERs).

- Serve as the primary contact for US product safety inquiries, escalations, and Health Authority requests.

4. Regulatory Compliance & Quality Oversight

- Maintain readiness for inspections and audits; manage findings, corrective actions, and CAPAs to closure.

- Keep current with evolving regulatory requirements and provide insights to support REMS and safety risk management strategy.

- Participate in FDA interactions, REMS negotiations, advisory boards, and industry forums.

Essential Requirements:

- Bachelor ' s degree in Health Care / Life Sciences required; advanced degree preferred (PharmD, PhD, or MD).

- 10+ years of PV leadership experience, including risk management planning and operational execution.

- Minimum of 8 years pharmaceutical industry experience is required.

- Strong knowledge of FDA REMS requirements, US pharmacovigilance regulations, and audit/inspection management.

- Proven leadership, communication, influencing, and decision-making capability.

- Strong executive presence and ability to manage multiple high-priority initiatives.

- Expertise leading large-scale strategic initiatives related to drug development and regulatory requirements.

- Deep understanding of risk management principles and best practices for REMS implementation.

Desirable Skills:

- Familiarity with safety databases, REMS platforms, and data analytics tools.

Novartis Compensation and Benefit Summary

The salary for this position is expected to range between $204,400 and $379,600 per year.

The final salary offered is determined based on factors like relevant skills and experience and may be reviewed periodically. Novartis may change the published salary range based on company and market factors. Compensation includes a performance-based cash incentive and eligibility for annual equity awards.

US-based eligible employees receive a comprehensive benefits package including health, life, disability benefits, 401(k) with company match, and generous time off.

Join Novartis and play a defining role in advancing patient safety and regulatory excellence in the United States. Apply now to be part of a purpose-driven organization reimagining medicine for patients worldwide.

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.

部门
Development

Business Unit
Development

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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