NOVARTIS

Senior Director, US Risk Management & Product Safety (REMS)

Job ID
REQ-10076170
Sep 10, 2026
LOC_US

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.

Role Requirements

Division
DIV_GD
Business Unit
Development
Location
LOC_US
Site
East Hanover
Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation
Functional Area
FCT_RD
Job Type
Full time
Employment Type
Regular
Shift Work
No
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