NOVARTIS

Group Head, Global Aggregate Reports & Risk Management

Job ID
REQ-10011542
Ago 29, 2024
Spagna

Sommario

Monitors and audits the company's drug, biologics or medical devices surveillance program including the intake, evaluation, processing and follow-up on adverse reports. Participates in the resolution of any legal liability and in complying with government regulations. Ensures accurate receipt, maintenance and assessment against product labeling. Reports events or reactions as required by regulatory agencies including adverse events data from clinical trials, spontaneous or solicited sources, periodic and experience reports. May provide trending and safety signal detection and assessment. Supports all clinical trial activity and post marketing.

About the Role

The Group Head, Global Aggregate Reports & Risk Management, Leads a group of Senior Global Risk Management Plan Managers as well as Senior Medical Writers and AR&RM Analysts in the development of robust and feasible Risk Management Plan strategies and Aggregate Reports for assigned high priority products / therapies, aligned with the benefit-risk profile of the products and supported by complex stakeholder matrixes.

Your key responsibilities, but not limited to;

- Responsible for timely high-quality deliverables either through direct involvement in processes or through assignments taking into consideration individual workload, experience, location, business needs and individual development needs. Interacts with GPTs and Functions (eg. GPH, HPS, Medical Writing, Regulatory Affairs) to ensure proper prioritization of programs and assign adequate resources. Aligns the support provided by Global (Sr) RMP Managers/ (Sr) Medical Writers/ AR&RM Analysts to the Global teams in developing and maintaining the Safety RMPs, RMP strategy and Aggregate Reports with business rules, regulatory guidance's and company standard operating procedures.
- Responsible for recruiting, developing, retaining (Sr) Global RMP Managers/ (Sr) Medical Writers/ AR&RM Analysts, developing and implementing an onboarding program for new hires. Provides operational and strategic guidance on RMP & AR processes, policy, templates, and training. Responsible for AR & RM team objectives according to company and department priorities, development plans and ongoing feedback on performance of direct reports.
- Member of the AR&RM Leadership Team. Collaborates with Global Head Aggregate Reports & Risk Management in setting the department's objectives and achieving them.
- Advises and influences the organization regarding Aggregate Reports & Risk Management concepts, strategy, and processes, relevant for product submissions and launches worldwide as well as for lifecycle management by close connection with stakeholders and industry peers.

- Guides a cross-functional matrix in the development of tools for RMP preparation, implementation tracking, working practices and guidelines, implementation of regulatory guidance's and Safety RMP project management.
- Acts as AR&RM Subject Matter Expert (SME) in inspections and audits as, including handling of pre-inspection/audit requests, participating in interviews with inspectors/auditors, and supporting CAPAs.
- Acts as AR&RM SME for assigned collaborations at early stages of partnerships, e.g. integrations, mergers and acquisitions. Influences these collaborations beyond Patient Safety, in global and local cross-functional and cross-divisional aspects of RMP, e.g. Regulatory Affairs, Marketing, Countries, which impact worldwide launches.
- Represents AR&RM in MSRB, GLC, GPTs & SMTs and other relevant boards / teams and provides expert opinion as required.
- Evaluates the impact and ensures compliance in collaboration with OPEX of worldwide regulations and industry practices on current AR&RM plans strategy, processes, and tools (e.g., ensures the templates and internal guidance's on strategy are in accordance with new/changing regulations). Drives the internal alignment on the company position with multiple functions and boards involved. Oversees the Global Teams' strategies for AR & RMP related responses to Health Authorities.
- In collaboration with OPEX and the AR&RM office, designs, develops, and maintains metrics to monitor quality of RMPs & AR, and escalates to Head of department, QPPV, PS&PV leadership and cross-functional boards any potential risk and issues.
- Provides input into the development of regular and up-to-date AR & RM training to the organization (namely SMT/GPTs, Medical Safety, Regulatory, Quantitative Safety and Epidemiology, Clinical, Medical Affairs).
- Deputizes for the Global Head Aggregate Reports & Risk Management e.g. MSRB for AR & RMP related aspects, and strategic initiatives.
- Deputizes for other Group head when required supporting their team.

Educational Background:

Scientific Degree required. Life sciences degree desirable. Advanced degree (Masters, MD, PharmD or PhD) required.

Languages:

Fluent in spoken and written English.

Why Novartis?

766 million lives were touched by Novartis medicines in 2021, and while we're proud of this, we know there is so much more we could do to help improve and extend people's lives.

We believe new insights, perspectives and ground-breaking solutions can be found at the intersection of medical science and digital innovation. That a diverse, equitable and inclusive environment inspires new ways of working.

We believe our potential can thrive and grow in an unbossed culture underpinned by integrity, curiosity, and flexibility. And we can reinvent what's possible, when we collaborate with courage to aggressively and ambitiously tackle the world's toughest medical challenges. Because the greatest risk in life, is the risk of never trying! Imagine what you could achieve here at Novartis!

Commitment to Diversity & Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to all individuals. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to receive more detailed information about the essential functions of a position, please send an e-mail to diversity.inclusion_ch@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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

Divisione
Development
Business Unit
Innovative Medicines
Posizione
Spagna
Sito
Barcelona Gran Vía
Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmacéutica, S.A.
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Job ID
REQ-10011542

Group Head, Global Aggregate Reports & Risk Management

Apply to Job

Source URL: *https://prod1.adacap.com/careers/career-search/job/details/req-10011542-group-head-global-aggregate-reports-risk-management*

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. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Barcelona-Gran-Va/Group-Head--Global-Aggregate-Reports---Risk-Management_REQ-10011542
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Barcelona-Gran-Va/Group-Head--Global-Aggregate-Reports---Risk-Management_REQ-10011542