Country Patient Safety Head - France

Job ID
REQ-10023055
Feb 12, 2025
France

Summary

We are hiring a Country Patient Safety (Pharmacovigilance) Head !

Location : Rueil Malmaison - Hybrid

In collaboration with the global patient safety and local leadership, the Country Patient Safety Head establishes and drives the Patient Safety (PS) strategy and operational excellence at country level, in compliance with the national and international regulations/standards/guidelines and corporate procedures, for all marketed and investigational products - drugs and medical devices - under the responsibility of all Novartis companies and divisions.

About the Role

Key responsibilities:

- In collaboration with the Regional Head (RH), provide key leadership skills based on expertise to the country to meet the strategic vision and regulatory requirements. Key member in the country organization in demanding local organization that has high commercial and regulatory visibility. Key member of the local leadership team or influencing local leadership team to assure the country is meeting its regulatory obligations to the local health authority.
- As defined by local regulations act as the National/Local Qualified Person or Local Contact Person for Pharmaco-device vigilance in the country (ies) and act as the single point of contact with the Local Health Authority on a 24-hour basis concerning Pharmaco-device vigilance matters.
- Monitor internal compliance for local processing and external compliance (regulatory reporting) according to defined timelines. Ensure that locally delayed safety cases or aggregate reports are properly captured, investigated and root causes addressed through any corresponding corrective/preventative action. Notification and escalation of any late case/submission to Pharmaco-device vigilance Compliance (PVC) and to QPPV/Countries & Regions.
- Drive the impact assessment of new local pharmacovigilance-related legislation and provide strategic support to Global PS organization on local PV matters and impact of any changes at country and/or global levels.
- Ensure the local Pharmaco-device vigilance requirements are met. Ensure Novartis tools/systems configurations are in line with the specific local requirements to guarantee that the Country Organization receives all the safety information needed to meet local legislation (National Health Authority, Ethic Committees, etc.).
- In collaboration with Regulatory Affairs (RA), ensure processes are in place to answer fully and promptly any safety related requests from Local Health Authorities; ensure alignment with Global Line Functions/

QPPV office in all safety-related responses, as applicable.
- As a senior member of QPPV-CPSH network, proactively contribute for the continuous monitoring and awareness of any emerging safety concerns at local level affecting the safety profile of the medicinal products for which Novartis group of companies MAHs hold authorizations. Collaborate together with RA in the implementation of urgent regulatory actions at country level, as required.

Essential Requirements:

- Health Care Sciences Professional (e.g. Medical Doctor, Nurse, Pharmacist) or equivalent education, training and experience
- Fluent in both written and spoken English and French
- Minimum 7 years' experience in drug-safety or pharmacovigilance (preferred) and/ or experience in pharmaceutical industry.
- Minimum 2-3 years of demonstrated leadership and accomplishment in all aspects of patient safety in a local/matrix environment in the pharmaceutical industry.
- Experience in PV audits and inspections

Desirable Requirements:

- Demonstrated track record to successfully lead/work in interdisciplinary global teams; leading, planning, and prioritizing activities simultaneously on multiple projects;
- Experienced leader in a matrix organization, including ability to influence and provide guidance and direction to team members.
- Demonstrated ability for innovative and big picture thinking.

You'll receive:

- Attractive salary range
- An annual bonus
- A focus on your career development
- Access to our Quality of Life at work program
- Flexible working
- Advanced social coverage for you and your loved ones
- 27 days of paid leave & 14 days of RTT per year
- Various employee recognition programs

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.

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

Development
Business Unit
Innovative Medicines
Location
France
Site
Paris Headquarter (Novartis Pharma S.A.S.)
Company / Legal Entity
FR12 (FCRS = FR012) Novartis Pharma S.A.S.
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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