# Patient Safety Manager

Job ID
REQ-10003344
Sep 04, 2024
France

## Summary

Suit et audite le programme de contrôle des médicaments, produits biologiques ou médicaux de l'entreprise, dont la réception, l'évaluation, le traitement et le suivi des rapports préjudiciables. Participe à la résolution de toute obligation légale et au respect des règles gouvernementales. Assure une réception, maintenance et évaluation précises face à l'étiquetage des produits. Signale les incidents ou réactions selon les exigences des régulateurs, y compris les données des effets négatifs des essais, les sources spontanées ou sollicitées, les rapports périodiques et d'expérience. Peut fournir tendances et détection et évaluation des signaux de sécurité. Soutient toutes les activités d'essais cliniques et après vente

## About the Role

**Key Responsibilities:**

- To be the accountable for specific operational vigilance process(es) at the Country Organization
- To mentor less experienced staff, maintaining a professional network of key contacts and role model Novartis values and behaviors.
- Ensure oversight and compliance in terms of reporting/submission/distribution of safety reports/updates/information (e.g., SAE, SR, IN, SUSAR, PSUR, DSUR, changes in risk-benefit profile) to Local Health Authorities (LHA) according to regulatory requirements and Novartis procedures.
- Work in close collaboration other local and global medical safety functions to ensure accurate evaluation of safety data.
- Interact and exchange relevant safety information with Health Authorities, other functional groups, third-party contractors, and PS associates, as applicable.
- Monitor national pharmacovigilance regulations and provide update to global PS organization.
- Set up, update, and implement local procedures to ensure compliance with PS global procedures and national requirements.
- Ensure local PS-related RMP commitments are executed and properly documented.

**Essential Requirements:**

- Education : Health Care Sciences Professional (e.g. Medical Doctor, Nurse, Pharmacist)
- Excellent communications and negotiation (networking) skills.
- Quality focused and results oriented.
- 2 years' experience in pharmacovigilance or equivalent field
- Knowledge of national and international regulations for pharmacovigilance

**Desirable Requirements:**

- Fluent in both written and spoken English and French
- Project management skills

**Why Novartis?** Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

**You'll receive:** You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards

**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.

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**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

Division
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
CDI
Shift Work
No
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