

## Patient Safety Manager

Job ID  
REQ-10003344

9月 04, 2024

France

### 摘要

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 réglementaires. Participe à la résolution de toute obligation légale et au respect des réglementations gouvernementales. Assure une réception, maintenance et évaluation précises face à l'étiquetage des produits. Signale les incidents ou actions selon les exigences des régulateurs, y compris les données des effets indésirables 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>

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部门

Development

Business Unit

Innovative Medicines

地点

France

站点

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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