

# Country Patient Safety Head

Job ID

385632BR

Apr 17, 2024

Philippines

## Summary

Our mission is to discover new ways to improve and extend peoples' lives. Bringing life-changing medicines to millions of people, Novartis sits at the intersection of cutting-edge medical science and innovative digital technology. As a global company, the resources and opportunities for growth and development are plentiful including global and local cross functional careers. Establish and drive Patient Safety (PS) strategy and operational excellence at country level, in compliance with the national and international regulations, standards or guidelines and corporate procedures, for all marketed and investigational products - drugs and medical devices - under the responsibility of all Novartis companies and divisions. As Country Patient Safety Head, you will head the local patient safety department will ensure the oversight of the quality management system for the patient safety system at local level, in collaboration with the local leadership, local, regional and Quality Assurance (QA) function.

## About the Role

### Your Responsibilities:

#### Your responsibilities include, but not limited to:

- 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]
- Act as the CPSH for all Novartis divisions and group companies [CPSH may delegate the activities to a deputy (CPSH Deputy) but the ultimate responsibility remains with the CPSH. Delegation should be clearly detailed]. Key member of the local leadership team and/or influencing local leadership team to assure the country is meeting its regulatory obligations to the local health authority. Partner management at a senior level in the local organization and at the global level in PS.
- Ensure oversight of the structure and performance of Novartis PV System at local level, in order to promote, maintain and improve compliance. Ensure access to all information sources maintained to lead all aspects of structure and performance of the PV system at local level.
- 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.
- Supervise and assess the performance and efficiency of PV 3rd parties in line with the applicable regulations, agreements and standard operational/ working procedures in place. In collaboration with QA and Vendor Management functions, ensure corrective and/or preventive actions are implemented in case

contractual commitments are not met, as applicable.

- Drive the local impact assessment of new local pharmacovigilance-related legislation and provide support to Global PS organization on local PV matters and local change impact. Ensure the local Pharmacovigilance requirements are met. Ensure Novartis tools/systems configurations are in line with the country-specific requirements to guarantee that the Country Organization receives all the safety information needed to meet local legislation
- 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. In cooperation with the QA applicable groups, lead any local Pharmacovigilance inspection and/or Pharmacovigilance audit and proactively, cooperate in the implementation of any corrective/ preventative action as determined by auditors/ inspectors. Contribute as Pharmacovigilance SME, in other internal Novartis audits and/or third party audits, as required.
- Contribute for the continuous monitoring 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. Ensure the country oversight of Patient Oriented Programs (POPs) held at local level, in line with Novartis procedures and applicable regulations/ standards/ guidelines. Act as the operational manager of the POP Champion Lead/ Manager/ Specialist for the country

#### **What you'll bring to the role:**

- Health Care Sciences Professional (e.g., Medical Doctor, Nurse, Pharmacist) or equivalent education, training and experience
- 8-10 years of working experience in drug-safety or pharmacovigilance (preferred) and/ or experience in pharmaceutical industry.
- Good knowledge of regional and local requirements relating to patient safety
- Working knowledge of PV-processes, covering compliance, databases, procedures, QA, training.
- Ability to lead and provide guidance and direction to team members.
- Critical thinking, Quality & Focus Oriented
- Ability to lead, plan and prioritize activities simultaneously. Good communication and networking 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>

**Join our Novartis Network:** If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: <https://talentnetwork.novartis.com/network>

<http://www.youtube.com/watch?v=B88bPEKkDI4&t=1s>

**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>

Division

Development

Business Unit

Pharmaceuticals

Location

Philippines

Site

Makati City

Company / Legal Entity

PH03 (FCRS = PH003) Novartis Healthcare Philippines, Inc

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

385632BR

## Country Patient Safety Head

[Apply to Job](#)

---

**Source URL:** <https://www.novartis.com/ph-en/careers/career-search/job/details/385632br-country-patient-safety-head-0>

### List of links present in page

- <https://www.novartis.com/about/strategy/people-and-culture>
- <https://www.novartis.com/careers/benefits-rewards>

- <https://talentnetwork.novartis.com/network>
- <http://www.youtube.com/watch?v=B88bPEKkDI4&t=1s>
- [https://novartis.wd3.myworkdayjobs.com/en-US/Novartis\\_Careers/job/Makati-City/Country-Patient-Safety-Head\\_385632BR](https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Makati-City/Country-Patient-Safety-Head_385632BR)