# Country Patient Safety Head West Africa

Job ID
REQ-10046300

6月 06, 2025

Ghana

## 摘要

Establish and drive 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. As CPSH, head the local PS department will ensure the oversight of the quality management system for the PV system at local level, in collaboration with the local leadership/local/regional Quality Assurance (QA) function.

The CPSH has direct responsibility for the West Africa cluster that includes the following countries identified as part of the WA cluster organization: Benin, Burkina Faso, Cameroon, Cape Verde, Central African Republic, Chad, Congo Democratic Republic, Gabon, Ghana, Guinea, Guinea-Bissau, Guinea Equatorial, Ivory Coast, Liberia, Mali, Mauritania, Niger, Nigeria, Senegal, Sierra Leone and Togo.

## About the Role

**Major accountabilities:**

- **Leadership:** Key member of the local leadership team and/or influencing local/cluster leadership team to assure the country is meeting its regulatory obligations to the local health authority. Stakeholder management at a senior level in the local organization and at the global level in PS.
- **Single point of** contact: 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. CPSH may delegate the activities to a deputy (CPSH Deputy) but the ultimate responsibility remains with the CPSH.
- **Country Patient Safety Head (CPSH)**: 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 documented**.**
  **Management of Safety Information:** Ensure oversight of the structure and performance of Novartis PV System at local level, to promote, maintain and improve compliance covering the following aspects:
- Local Procedures.
- Case Processing (triage/ documentation; translation; data-entry; follow-up activities and archive, as applicable).

- Expedite ICSR reporting and aggregate reporting (PSUR, DSUR, ASR) in relation to quality, accuracy, completeness and timelines, as applicable.
- Cooperation and oversight of the implementation of local RMP commitments.
- Training of MAH personnel in relation to PV.
- Local Licensing agreements.
- Pre- and post-authorisation safety studies, with appropriate PS input as required.
- Patient Oriented Programs (POPs), Social Media Listening and Digital Engagement Initiatives.
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- **Compliance with Local Legislation:** Ensure the local Pharmaco-device vigilance 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 (i.e. National Health Authority, Ethic Committees, etc.).
- **Health Authority Requests:** In collaboration with Regulatory Affairs (RA), ensures processes are in place to fully and promptly answer any safety related requests from Local Health Authorities in the region; ensures alignment with RH/CH/Global Line Functions/ QPPV office in all safety-related responses, as applicable
- **Audits, Self-assessments and Inspections:** In cooperation with the QA applicable groups, manage any local Pharmaco-vigilance inspection and/or Pharmaco-device vigilance audit and proactively, co-operate in the implementation of any corrective/ preventative action as determined by auditors/ inspectors. Contribute as Pharmaco-device vigilance SME, in other

internal Novartis audits and/or third-party audits, as applicable at the regional, cluster and country level.

- **EUQPPV-CPSH-Network:** 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 with RA in the implementation of urgent regulatory actions at country level, as required.
- **POP Governance**: Ensure the oversight of Patient Oriented Programs (POPs) at the region level, in line with Novartis procedures and applicable regulations/ standards/ guidelines.
- **Documentation:** Ensures oversight of all information sources maintained to oversee structure and performance of the PV system at local level.
- **Monitoring internal and external compliance of Safety Reports:** At the local level, monitor internal compliance for local processing and external compliance (regulatory reporting) according to defined timelines. Ensure that 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.
- **Oversight of local PV third parties working on behalf of Novartis**: Monitors and assesses the performance and productivity 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, ensures corrective and/or preventive actions are implemented in case contractual commitments are not met, as applicable.
- **Regulatory Intelligence:** Supports the RH/CH/CPSH to drive the impact assessment of new local pharmacovigilance-related legislation in the region/cluster/country and provides operational expertise and strategic support on local PV matters and impact of any changes at region/cluster/country and/or global levels.

**Key performance indicators:**

- Quality (i.e. accurate, complete and timely) of local PV deliverables
- High PV compliance at country level
- Country PS team adequately resourced and with high competencies
- Country PS team audit/inspection ready
- Successful audit/inspection outcomes (no critical findings under PS responsibility)

**Minimum Requirements:**
**Work Experience:**

- Minimum 5 years ' experience in drug-safety or pharmacovigilance (preferred) and/ or experience in pharmaceutical industry

**Skills:**

- Good knowledge of regional and local requirements relating to PV;
- Working knowledge of PV-processes, covering compliance databases, procedures, QA, training.
- Ability to lead, plan and prioritize activities simultaneously.
- Ability to manage and provide guidance and direction to team members.
- Strategic thinking;
- Quality and focus oriented;

- Good communication and networking skills.
- Computer/IT systems literacy

**Languages :**

- Fluent in both written and spoken English
- Knowledge of other languages desirable

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部门
Development

Business Unit
Universal Hierarchy Node

地点
Ghana

站点
Ghana

Company / Legal Entity
GH01 (FCRS = GH001) Novartis Ghana Limited

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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