# Country Patient Safety Head Hungary

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REQ-10037604
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Ungarn

## Summary

You will establish and drive patient safety 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 Country Patient Safety Head you will lead the local PS department ensuring the oversight of the quality management system for the PV system at local level, in collaboration with Countries & Regions Regional Head/ Manager and the local leadership.

## About the Role

**Role responsibilities:**

**Leadership:** 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. 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]

**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

**Monitoring internal and external compliance of Safety Reports:** 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.

**Oversight of local PV third parties working on behalf of Novartis:** Monitor and assess 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, ensure corrective and/or preventive actions are implemented in case contractual commitments are not met, as applicable.

**Regulatory Intelligence:** 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.

**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), 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

**Audits and Inspections:** In cooperation with the QA applicable groups, manage any local Pharmacovigilance inspection and/or Pharmaco-device vigilance audit and proactively, cooperate 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 required.

**QPPV-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 together with RA in the implementation of urgent regulatory actions at country level, as required.

**POP Governance**: 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 (ies), as applicable.

Requirements for the role:-

- Minimum 5 years in PV/Drug Safety
- Knowledge of EU & Hungarian PV requirements
- Demonstrated leadership

- Must be located in Hungary
- Must have a degree in Life science, Chemical or Chemical Engineering
- Must speak Hungarian

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Innovative Medicines
Standort
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HU02 (FCRS = HU002) Novartis Hungary
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Employment Type
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