



JOB TITLE:	Country Safety Head
REPORTS TO:	Affiliates PV Head with dotted line to Country Manager
BUSINESS AREA:	Pharmacovigilance
DATE AMENDED:	

JOB PURPOSE

The Country Safety Head (CSH):

- Is responsible for **country/ies**
- Serves as the local PV contact for the authorities, accountable for PV inspections and is nominated as local Responsible Person for Pharmacovigilance (RPP/QPPV) for the CHC products where applicable per national regulations. Designate a back-up who replaces him/her when he/she is out of the office
- Is recognized as the key leader for all PV related activities at country level, including but not limited to case management, local safety surveillance, signal detection, risk management and risk mitigation activities, patient support programs and market research programs
- Ensures that local PV activities are performed in compliance with the Global PV policies, as well as global, regional and local PV regulations to warrant safe and appropriate use of CHC products on the market in the assigned country(ies)
- Establishes and maintains a robust and efficient local PV system by ensuring the availability and implementation of proper systems/procedures tools and training. Work closely with the Affiliates PV Head/Country Manager to ensure adequate resources and budget are allocated.
- Builds close and robust relations/collaboration with the in-country partner functions, including but not limited to Medical, Regulatory, Quality, Commercial, Legal, and Country Manager.

KEY RESULTS/ACCOUNTABILITIES



Local and Global Partnership

Local:

- Represent PV in interactions with local GxP and non GxP functions, to optimize coordination and collaboration in areas of overlapping interests:
- Build and maintain robust collaboration/interaction with the in-country partner functions, to carry out and monitor local PV activities, in compliance with PV regulatory requirements and company procedures/guidelines, and particularly

Global:

- Identify issues or dysfunction in the assigned country(ies) and escalate to the Affiliates PV Head,
- In case of local PV outsourcing activities, collaborate with Global PV to implement the best outsourced capabilities
- Interact with the Global PV for any questions related to the safety profile of CHC products originating from HA or any other sources

Organization and maintenance of local PV Quality system

- Establish and implement processes in compliance with regional/local PV regulations and global procedures and cooperate with the local Quality Head to document them in local Quality Documents as appropriate
- Ensure maintenance of local quality documents owned by PV to include documented reviews, gap assessments and revisions as per global requirements.
- Develop and maintain the local PV System Master File in accordance with the global standards
- Ensure that education and training on PV and relevant safety topics within the local organization are performed including documentation of attendees and topics covered (i.e. PV Awareness, training of service providers and manufacturing sites)
- Manage local compliance metrics generation and ensure data capture in the appropriate tools.
- Document PV process non-compliance to include investigation, Root Cause Analysis (RCA), Corrective Actions/Preventive Actions (CAPAs) implementation and coordinate related tracking activities with local Quality Head.
- Warrant audit and inspection readiness of the local PV system (auditable trail of all PV activities performed locally is maintained and readily available) with key stakeholders (i.e. Quality, Medical, Regulatory)
- Complete in timely manner audit and inspection observations in close interaction with Global /Local Functions

Organization and Maintenance of PV Operating & Safety Management System

In compliance with PV regulatory requirements and company procedures/guidelines,

- Monitor continuously in-coming communication to ensure the detection and appropriate management of in-coming PV data (ICSRs and other safety related information) to report them in timely manner to Global PV Operations and subsequently to external stakeholders, such as HAs, partners.
- Handle appropriately local periodic reports, including periodic safety reports (PSRs) and periodic reviews, and contribute together with Global PV, Clinical Operations and RA departments to the planning for PSRs ,
- Screen local scientific / medical literature and manage relevant abstract/articles accordingly



- Ensure appropriate implementation and monitoring of PV requirements for global, regional and local programs (e.g. Patient Support Program, Market Research, Managed Access Program...), and company sponsored digital media
- Screen and analyse national regulations, and forward any future/new/updated PV regulation to the Affiliates PV Head
- Secure that for all global/local Business Partner agreements, requiring safety provisions, a local SDEA or PV Clause is set-up, implemented and maintained as appropriate.
- In case of local outsourcing of PV activities to third parties (i.e. vendors/service providers/CROs), Manage contract/work order with local service provider, monitor the appropriate execution of outsourced activities and take the appropriate measures in case of deviations
- Support the Global PV with local safety surveillance activities
- Handle/escalate product safety alerts in timely manner
- Contribute to the development of local RMP, when applicable, with the support and validation of the Risk Management Expert. Track the actual implementation of additional Risk Minimization Measures (aRMMs)
- Ensure that PV unit is involved in reviewing relevant safety sections of local documents, owned by other affiliates entities, such as labeling, contracts with third parties and local study protocols.

KEY WORKING RELATIONSHIPS

- Affiliate PV Head
- Country Medical/Regulatory Teams and Country Manager
- QPPV
- Global PV Operations Team
- Global Medical Safety Team
- CSH Network

SKILLS, EXPERIENCE & KNOWLEDGE REQUIREMENTS



Competencies

- Knowledge of national PV regulations and international regulations regarding safety requirements as well as industry standards
- Leadership skills; problem-solve, prioritize, take initiative and meet challenges
- Good written and verbal communication skills. Good level of speaking/writing English.

Education

- Medical Doctor, Pharmacist, Pharm D, Veterinary Doctor, Health Sciences PhD, MPh or Master Degree with two or more years of pharmacovigilance/clinical development experience.

Experience

- Experience with pharmacovigilance systems and safety related product management in both clinical development and marketed products
- Appropriate experience with Regulatory Agency interactions

Key Dimensions

- Report to Affiliates PV Head Affiliates with dotted line to Country Manager

Approved

Date:	
Job holder:	
Manager:	