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Pharmacovigilance in India and emerging markets: An industry perspective

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Development and implementation of evidence-based, public-health focused, collaborative, globally electronic and regulatory compliant approach is need of hour to gain comprehensive Pharmacovigilance (PV) system. Emerging markets of India, SE Asia, Russia, Latin America, Middle East and North Africa have their PV programs. The authors discuss development of a model for uniform PV data input-output across industry. Authors contemplate Data collection; Data analysis; Data processing; Medical Review and Data distribution systems as basic PV process. Data collection systems should include detailed process of collecting various adverse events (AEs) from Literature searches, healthcare professionals (HCP), non-HCP, spontaneous, clinical trials, patient registries, post marketing surveillance etc. Data should be processed in CIOMS Form I by using ARGUS, ARISg, MedDRA, WHO drug dictionary and company drug repository or local regulatory AE form, etc. It should be medically reviewed followed by distribution to respective regulatory authorities where thorough signal identification, prioritisation and investigation will be performed. Signal detection can be done by using Medline/PubMed, Springer, OVID database, reactions weekly, local publications etc. Non-English cases/literature reports should be translated to English via authorised vendor or in-house translation system. Safety data from license partners and third party manufacturers should be collected and processed by maintaining Safety Data Exchange Agreements (SDEA). PV model can be fully in-house end to end or part in-house and part outsourced or fully outsourced. In conclusion, an effective implementation of PV activities like robust PV systems, signal detection and SDEAs could definitely yield robust patient safety data from India and emerging markets.

Biography

Shashidhar Swamy is Pharmacology postgraduate from JNTU Hyderabad, India. He is currently working as Head Pharmacovigilance at Wockhardt Ltd (India and Emerging Markets). He has rich experience in Pharmacovigilance process set up and handling regulatory inspections. His previous Pharmacovigilance assignments were with Novartis Pharma Ltd and Pfizer Inc (Wipro Ltd and Mahindra Satyam Limited). He has marketing experience with Sanofi Aventis and Ranbaxy Laboratories Ltd. He has participated in many conferences and presented posters at various events. His cumulative pharmaceutical industry experience is more than 9 years.

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