

PHARMACOVIGILANCE & DRUG SAFETY SUMMIT

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Challenges for sustenance

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With the ever-increasing requirement from various regulatory authorities across the globe, the marketing authorization holders (MAHs) are required to comply with these requirements. To meet the expectations from multiple regulators, it becomes difficult for MAHs to sustain the team, resources and also to manage the global team within the budget. One of the challenges is to have global compliance in terms of regulatory reporting, identification, assessing, reviewing the ICSRs and reporting them on-time. At the same time, the ICSRs are to be exchanged with the global partners. Right at the start and sustain the rightness through various processes including the risk based audits of various functions is the key to this compliance. Well trained and experienced resources and retention strategy play important role in the PhV system. Automation processes which are validated and compliant to the requirements help MAH to minimize the manual inputs wherever possible e.g., literature imports, identification of key index term, using auto mails for follow up communications, generating various reports like KPI dashboard and compliance reports. The safety databases to be used to its fullest capabilities, right IT partners (in-house or outsourced) helps in this to align.

Biography

Abhay Chimankar is a Physician by profession, Global Leader with expertise in drug safety and pharmacovigilance regulatory affairs with additional experience in medical writing, clinical trials, BA/BE monitoring and auditing. He is well-versed in global regulatory guidelines and speaker at international conferences and is known as a keen planner, strategist, and implementer with solid track record of results that deliver business value through streamlined PV operations. His areas of PV expertise include: Pharmacovigilance guidelines in key areas of the globe, with in-depth knowledge on patient safety, practical implications of EU GVP, particularly all effective modules, establishing PV operations, Argus implementation and electronic gateway setup and compliance with quality standards, SOPs, ICH-GCP and/or other guidelines. He has experience previously working in Cipla Ltd, TCS and Novartis. He is currently working with Pharmaviz Pvt. Ltd. as the CEO.

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