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Deep dive in aspects of pharmacovigilance for biologics, bio-similar and vaccines

Because no two biologic medicines are identical, post approval safety monitoring will be critical to detect potential differences in safety signals between a biosimilar, its reference product and other biosimilars. Post approval safety monitoring in the USA uses two signal detection systems: Spontaneous Reporting Systems (SRSs) and Active Surveillance (AS) systems. Both depend on accurate identification of the specific product(s) dispensed or administered to patients, which may be compromised when products from multiple manufacturers share common drug nomenclature or coding. The purpose of this study is to describe the entire process of ICSR and signal detection and automation at our PVG center.

Biography

Ujwala V. Salvi has over 15 years of experience across the Global and local Pharmaceutical/CRO, Tier I Medical Devices and BPO industry. She is Doctorate in Applied Biology & MBA in Healthcare from Indian Institute of Management, Kolkata. QPPV for Nucleon Therapeutics, Trained in Six Sigma Black Belt and various Project management tools, with core experience in a wide range of Therapeutic Areas, and worked at all stages of clinical development from Phase II to production of clinical documentation necessary for product license applications. She has worked in large global operations, managed strategic relationships, and played a key role in winning new business, setting up off-shored partnerships and in identifying new BU service lines and growing existing ones. Her areas of expertise include Pharmacovigilance, Clinical Data Management, Clinical Trial operations, Risk Based Monitoring, Medical Writing and data publication, and feasibilities of new drug development and Analytics.

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