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Benefit and safety risk management and pharmacovigilance (PV)

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Although risk management activities and plans, increase companie's and Regulator's understanding of a product's risks, a broader requirement is moving to centre stage and to the continuous and rigorous review of available data to evaluate the balance between a product's benefits and its risks.companies must perform routine, ongoing PV activities for their products such as benefit-risk monitoring and managing spontaneous reports. These may be sufficient to address some, or even all, of a product's safety concerns. However, additional PV activities are often needed, which are usually classified as post-authorisation safety studies (PASS). These can include further clinical trials as well as non-interventional approaches, such as observational studies or patient registries.complex pharmacovigilance legislation in an evolving regulatory landscape has left drug makers searching for current, efficient and more meaningful solutions for their drug safety challenges, especially in the post-marketing arena. Post-marketing safety and risk management have witnessed a fundamental shift from safety monitoring to the benefit-risk paradigm with proactive signal detection and periodic benefit-risk evaluation being the key focuses. FDA has moved from RiskMAP to Risk Evaluation and Mitigation Strategy (REMS) and required post-marketing studies to collect real-world evidence to support NDAs/BLAs (FDAAA 2007). EMA has also introduced the new Good Vigilance Practice (GVP), which replaces the previous Volume 9A. The creation of sentinel observation networks by the Food and Drug Administration as well as PhRMA's Observational Medical Outcomes Partnership initiative are initial approaches to a new proactive paradigm of signal detection, and risk management; where consortiums of academic, government and industry centers of excellence will work on developing new methodologies to be incorporated into the proactive practice of drug safety.

Biography

Archana Mehrotra started her career in Pharmacy after completing her graduation in 1997 in Production of Injectables and was rewarded as Approved Chemist for Injectables Production by FDA, Maharashtra. She then worked as a Pharmacy Inspector in Maharashtra State Pharmacy Council, then after worked in industry as well as in teaching. She did her Post-graduation in 2003 and in May 2012 she completed her Doctorate. Her specialization is in Pharmaceutical Technology especially nanotechnology and solubilization techniques. She is a member of Novo-Trail Drug Discovery and Pharmaceutical Innovation Hub (P) Ltd; Bhopal and a member of Association of Pharmacy Professionals, Bhopal (M. P.) India.

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