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Seamless pharmacovigilance practices: Blurring the line between drug safety and pharmacovigilance

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Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems. Conventionally, it involves reporting individual cases or aggregate reports. Within the last decade, there has been a growing awareness that the scope of pharmacovigilance should be extended beyond the strict confines of detecting new signals of safety concerns. It involves ongoing processes to monitor an always evolving benefit/risk profile, with a well-established safety governance model across the enterprise and a solid underlying process for signal detection and management. There is an inherent challenge in bringing pharmacovigilance expertise development phase into the medicinal products for the first time; the weight of the established practices has resulted in a dichotomy between safety management in the pre-marketing and in the post-marketing phase, with many negative impacts. Many companies still refer to drug safety for pre-marketing activities and pharmacovigilance for post-marketing activities, while the essence is same. Pharmacovigilance contributions are essential for the development or the review of key study documents and processes such as protocol, investigator's brochure, safety management plan, core development safety label, DSUR/IND reports, safety signaling plan, etc. As per USFDA resources, from 2001 through 2010, the FDA approved 222 novel therapeutics (183 pharmaceuticals and 39 biologics). There were 123 new post-market safety events (3 withdrawals, 61 boxed warnings and 59 safety communications) during a median follow-up period of 11.7 years (Interquartile Range [IQR], 8.7-13.8 years), affecting 71 (32.0%) of the novel therapeutics. To reduce this, improvized strategies to collect safety data in premarketing stage is required for effective risk management post approval. Bringing the PV team early into the development phase team will create a critical continuum of safety expertise on the company's product, with positive impacts during its whole lifecycle and enhance the regulatory compliance.

Biography

Ripal Gharia has completed her MD in Pharmacology from Bhavnagar University in India. She is currently working as an assistant general manager, pharmacovigilance and medical Services at Cliantha Research Limited. She has experience in medical writing, regulatory affairs, pharmacovigilance and clinical trial management.

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