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Role of pharmacovigilance in drug development

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Pharmacovigilance (PV) is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or other drug related problem. PV collects, records, Adverse Drug Reactions/adverse drug events analyses and assesses the reports, promotes the safe use of drugs, creates suitable structures and means of communication needed to execute its tasks. PV is to recover patient care and safety, improve public health and safety, supply to the assessment of benefit, harm, effectiveness and risk of medicines, promote education and clinical training, support effective communication to public and encourage rational and protected use of medicines. The expansion of drug discovery and development is a long-term, competitive, expensive and complex process. Bringing the drugs from screening and identification of the drug as a compound to the market, takes several years of hard work. The process of discovering and developing a new drug involves an elaborate interaction between investors, industry, academia, patent laws, regulatory authorities, marketing and the necessity to balance secrecy with significance. The complete process of presenting a drug to the patients involves four stages. They are drug discovery, drug development, regulatory review, approval and marketing. PV is an iterative process focusing on detection of unidentified safety issues, identification of risk factors, quantifying risks and preventing patients from being adversely affected unnecessarily. PV requires submission of the reports on adverse events during clinical trials to regulatory authorities within a specified time frame, notification of such events to all investigators and ethics committees. Annual reports, a summary and analysis of all the serious adverse events, new safety findings from animal studies, and evaluations of benefit and risk are also required. PV plays a considerable role when the drug is commercialized. Reporting the safety reviews is mandatory for companies in a marketing phase. PV is a very essential and expected part of the drug discovery and development process. PV is essential to establish good clinical practices for improving the understanding of the drug safety issues during the drug development and it's post-approval.

Biography

Prabhakar Reddy Veerareddy is an accomplished researcher, eminent teacher in Pharmaceutical Sciences. Currently he is serving as Principal at College of Pharmacy, Palamuru University, Mahabubnagar, Telangana State, India. He has spent one year at Butler University, Indiana Polis, USA for Post-doctoral research and pursued his Doctoral thesis (Pharmaceutics) at Novel Drug Delivery Laboratories in Kakatiya University, India during 2005. He has attended many symposiums and workshops at the national and international level. He has 80 research publications in several national and international journals, and he guided 70 MPharm students and 6 PhD students.

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