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Abstract

Process Optimization and Role of Artificial Intelligence in Global Pharmacovigilance

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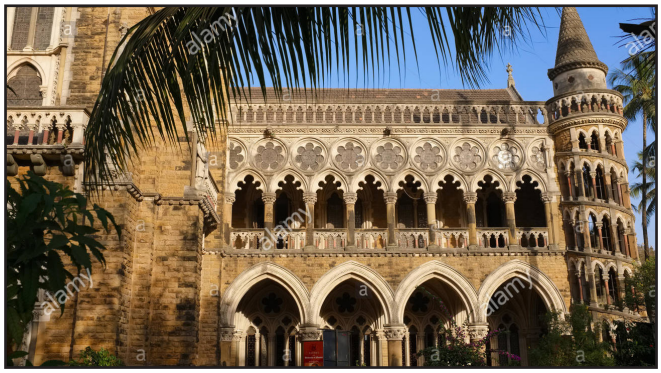
Abstract:
Pharmacovigilance is like a sunshade to describe the processes for monitoring and evaluating ADRs and it is a key component of effective drug regulation systems, clinical practice and public health programs. The number of Adverse Drug Reactions (ADRs) reported resulted in an increase in the volume of data handled, and to understand the pharmacovigilance, a high level of expertise is required to rapidly detect drug risks as well as to defend the product against an inappropriate removal. The current global network of pharmacovigilance centers, coordinated by the Uppsala Monitoring Centre, would be strengthened by an independent system of review. This would consider litigious and important drug safety issues that have the potential to affect public health adversely beyond national boundaries. Recently, pharmacovigilance has been confined, mainly to detect adverse drug events that were previously either unknown or poorly understood. Pharmacovigilance is an important and integral part of clinical research and these days it is growing in many countries. Today many pharmacovigilance centers are working for drug safety monitoring in this global pitch, however, at the turn of the millennium pharmacovigilance faces major challenges in aspect of better safety and monitoring of drugs. In this review we will discuss about drug safety, worldwide pharmacovigilance centers and their role, benefits and challenges of pharmacovigilance and its future consideration in healthcare sectors.

Pharmacovigilance as a tool for safety and monitoring: a review of general issues and the specific challenges with end-stage renal failure patients

Pharmacovigilance is instrumental in helping to ensure patient safety for both newly released drugs and those that are well established in the market. However, while pharmacovigilance procedures are strictly regulated in the clinical trial setting, post-marketing adverse event reporting is not well implemented or enforced. As such, the underreporting of adverse events, in relation to drugs that are on the market, is estimated to be in the region of 90%. The identification of drug safety issues in patients with complex diseases and extensive comorbidities is therefore particularly challenging.

This review defines the science of pharmacovigilance and the process of adverse event reporting, highlights the new directions that pharmacovigilance has taken, and provides insight for HCPs managing dialysis patients into the important role that they play in helping to shape the understanding of a drug's safety profile in order to continually enhance patient safety.



Biography:
Dr Ujwala Salvi is a Founder & CEO, at NUCLEON Therapeutics. She is MBA in Finance from IIM, Calcutta India, & Ph.d in Applied Bio from Mumbai Uni, has over 15 years of experience across the Global Pharma/CRO, Medical Devices & BPO industry.

Leading in Pharmacovigilance, Clinical operations & Regulatory Writing at Nucleon with well defined, GVP compliant Pharmacovigilance systems & SOP driven procedures in place and has an track records successful regulatory inspections from USFDA.

Areas of expertise include Pharmacovigilance, Clinical operations, CDM & Data Analytics, involved in key global industry forums such as the DIA, SCDM, CII and CPHI

Publication of speakers:

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