Manoj Sharma, J Pharmacovigilance 2014, 2:5
http://dx.doi.org/10.4172/2329-6887.S1.015

OMICS Group Conferences
Accelerating Scientific Discovery

3rd International Conference and Exhibition on
Pharmacovigilance & Clinical Trials
October 27-29, 2014 Hyderabad International Convention Centre, India

Pharmacovigilance: Patient safety in India

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In today's zero-tolerance drug safety environment, Pharmacovigilance has never been more important. To ensure patient safety, minimize costs, and assure compliance, life sciences firms must aggressively detect and manage emerging safety risks. The stringent regulations on safety monitoring and their periodical revision have led to increased safety data collection, analysis and regulatory surveillance, and increased costs. Thus, Pharmacovigilance has become a critical phase in clinical development programs. Pharmacovigilance is an important and integral part of clinical research. Safety and efficacy are the two major concerns about a drug. Adverse Drug Reaction is a recognized hazard of the drug therapy. The deficiencies in knowledge, attitudes and practices of resident doctors regarding ADR reporting needs urgent attention on priority basis, not only for the success of the pharmacovigilance program, but for better clinical management of the patients in general. Elderly aged ≥75 years were at increased risk of an ADR-related hospitalization. Adverse Drug Reactions (ADRs) are common causes of morbidity and mortality in both hospital and community settings. ADRs are responsible for about 5% to 20% of hospital admissions. Around 39,353 ADR's have been reported under Pharmacovigilance program in India till January 2013. Central Drug Standard Control Organization (CDSCO) has initiated a nationwide pharmacovigilance program under the aegis of Directorate General of Health Services (DGHS), Ministry of Health and Family Welfare, Government of India. This program is largely based on the recommendations made by the WHO in its document titled -Safety Monitoring of Medicinal Products - Guidelines for Setting up and Running Pharmacovigilance Center". A nationwide network with 25 peripheral centers, 5 regional centers, and 2 zonal centers was established, in a hierarchical fashion, with predefined tasks and responsibilities allocated at each level. The aim of Pharmacovigilance is to improve public health and safety, to contribute to the assessment of benefit, harm, effectiveness and risk of medicines, to promote understanding, education and clinical training.

Biography

Manoj Sharma has completed his PhD from Defence Research and Development Establishment (DRDE), Gwalior affiliated to Jiwaji University, Gwalior, Madhya Pradesh, India in April 2009. He is presently working as an Associate Professor in Pharmacology and Toxicology Department, School of Studies in Pharmaceutical Sciences, Jiwaji University Gwalior-India. He has published several research papers in journal of national and international repute. He received best paper award at DRDE Award Ceremony- 2009 at Defence Research and Development Establishment, Gwalior, India. He has authored / co-authored of four books and also applied for one patent. He has completed one project as Principal Investigator funded by DRDE, Gwalior and also completed 08 projects as team member during fellowship period. He has supervised 15 MPharm student`s dissertation and some students have been registered for PhD under his guidance. He has been nominated as "CPCSEA Nominee" by Ministry of Environment and Forest, Govt. of India in 2014.

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