REG.NO:D7635654-AFINJ JOHP-ISSN: 2348-7704

HEB JOHP

Journal of Hospital Pharmacy
An Official Publication of Bureau for Health & Education Status Upliftment
(Constitutionally Entitled as Health-Education, Bureau)

Materiovigilance: Understanding Its Concept and Practice in Global Health Care System

Vasavi Pachika[1], Vadla Nikitha[2], Vijaya Sindhuri.Gopu[3]*

Name of Corresponding Author: Vasavi Pachika, Associate Professor, Department of Pharmaceutics, St.Mary's College of Pharmacy, Secunderabad, 500025, Telangana, India.

Email Id: serviceheb@gmail.com

ABSTRACT:

The study aims to understand adverse events associated with medical devices, their classification, criteria for reporting such events, the reporting process, and the importance of creating awareness among healthcare professionals and users regarding medical device vigilance in countries like the United States, Europe, Japan, and India. Medical devices play a crucial role in diagnosing, treating, and preventing diseases in humans and animals; however, adverse events such as device malfunctions and failures have caused significant harm, including misdiagnosis and mistreatment. A systematic approach to identifying, collecting, reporting, and analyzing adverse events is vital. The Materiovigilance Programme of India (MvPI), approved by the Ministry of Health and Family Welfare on February 10, 2015, and launched on July 6, 2015, addresses such issues while promoting harmonization with other countries. Regulated nations classify medical devices based on their associated risks, and comparing these systems reveals gaps and provides insights for improving regulations. This study provides an overview of adverse event reporting systems in the US, Europe, Japan, and India, examining their current status, device classification, reporting criteria, processes, timeframes, and tools. A comparison of these systems highlights regulatory gaps and emphasizes the need to raise awareness among healthcare professionals and users to ensure patient safety and effective vigilance.

Keywords

Medical devices, Materiovigilance, Adverse events, medical device safety, Reporting system.

Access this Article Online	Quick Response Code:
Website: http://www.journalofhospitalpharmacy.in	
Received on 05/04/2025	
Accepted on 13/04/2025 © HEB All rights reserved	