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Regulatory Requirements on Pharmacovigilance as Per CDSCO in India Comparison with Japan

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ABSTRACT

Pharmacovigilance (PV) plays an analytical role in ensuring drug safety and public health. This research explores the regulatory frameworks and PV systems in India and Japan, focusing on the Central Drugs Standard Control Organization (CDSCO) and Pharmaceuticals and Medical Devices Agency (PMDA), respectively. Historical developments, adverse drug reaction (ADR) reporting systems, risk management protocols, and international harmonization practices are discussed.[1] India's PV system has evolved through programs such as the Pharmacovigilance Program of India (PvPI), whereas Japan's system emphasizes structured post-marketing surveillance (PMS) and risk management plans (RMPs). Although both systems have made significant progress, challenges such as underreporting in India and regulatory burden in Japan persist. This comparative analysis offers insights into upgrading global pharmacovigilance through interactive learning and harmonization.

Keywords: Pharmacovigilance, Regulatory Affairs, CDSCO, PMDA, ADR reporting, Risk Management.

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INTRODUCTION

The Rise of Pharmacovigilance and Regulatory Affairs

The safety and efficacy of pharmaceuticals are critical to the sustainability and integrity of healthcare systems. As therapeutic innovations accelerate globally, ensuring drug safety beyond initial approval has become a strategic priority for governments, regulators, and healthcare providers. Pharmacovigilance (PV) the science and practice of detecting, assessing, understanding, and preventing adverse effects or any other drug-related problem has thus emerged as an indispensable discipline within the pharmaceutical and public health landscape[2].

Pharmacovigilance operates at the intersection of clinical research, drug regulation, epidemiology, and patient safety. The importance of pharmacovigilance is underscored by the growing intricacy of medicinal products, including biologicals, gene therapies, and personalized medicines, which may elicit unexpected safety concerns once exposed to larger, more heterogeneous populations during post-marketing use. Additionally, in low- and middle-income countries (LMICs), such as India, where healthcare delivery systems are often fragmented, the burden of monitoring medicine safety and effectiveness requires robust infrastructure, trained personnel, and legislative backing. [3]

Regulatory affairs (RA), meanwhile, provide the administrative and scientific backbone for approving, licensing, and overseeing pharmaceutical products. RA professionals serve as vital intermediaries between pharmaceutical companies and government authorities, ensuring compliance with laws, filing investigational new drug applications (INDs), and maintaining lifecycle documentation. While the fields of RA and PV are distinct, they are mutually reinforcing: effective regulatory systems rely on sound pharmacovigilance to refine drug safety profiles and guide evidence-based policy updates. [4]

The Global Context

International organizations such as the World Health Organization (WHO), the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), and the Uppsala Monitoring Centre (UMC) have played pivotal roles in promoting harmonized standards for pharmacovigilance. The ICH E2 series (E2A to E2F), which governs safety reporting, periodic safety update reports (PSURs), and risk management planning, has been adopted in varying degrees by regulatory authorities worldwide. [5]

Pharmacovigilance is now viewed as a shared global responsibility. However, national regulatory environments differ markedly based on legal traditions, administrative capacity, pharmaceutical market maturity, and population health needs. Thus, comparative analysis of national PV

frameworks offers crucial insights for global health, especially when examining two divergent but influential systems such as those of India and Japan.[6]

India and Japan: Contrasting Contexts

India, one of the world's largest generic drug producers, has become an increasingly important node in global pharmaceutical supply chains. Its domestic pharmaceutical market is driven by both public-sector health programs and a robust private sector. The Central Drugs Standard Control Organization (CDSCO), under the Ministry of Health and Family Welfare, is the apex regulatory body responsible for new drug approvals, licensing, and pharmacovigilance. Since the launch of the Pharmacovigilance Program of India (PVPI) in 2010, India has sought to align itself with global PV standards. Despite these developments, India's system continues to face challenges such as underreporting of ADRs, lack of public awareness, and inadequate training of healthcare personnel in PV practices. [7]

Japan, by contrast, operates one of the most sophisticated pharmacovigilance ecosystems in the Asia-Pacific region. The country's regulatory framework is overseen by the Pharmaceuticals and Medical Devices Agency (PMDA), an independent administrative agency under the Ministry of Health, Labor and Welfare (MHLW). Japan is notable for its re-examination and re-evaluation systems, mandatory all-case surveillance for high-risk drugs, and rigorous implementation of risk management plans (RMPs)[8]. The Japanese Adverse Drug Event Report (JADER) database provides a structured and publicly accessible system for ADR data collection, which contributes to transparent regulatory decision-making.

Objectives of This Study

This paper aims to provide a comparative regulatory analysis of pharmacovigilance frameworks in India and Japan. The key research questions include:

- Trace the evolution of PV systems in India and Japan.
- Identify key organizational structures, ADR reporting, and risk management systems.
- Draw lessons from implementation, effectiveness, and challenges.
- Explore benefits of harmonization and mutual learning.

By addressing these questions, the article contributes to a growing body of scholarship on comparative pharmacovigilance and provides policy-relevant recommendations for improving drug safety governance.

Historical Overview of Regulatory Development

India	Japan
Pharmacovigilance in India emerged slowly post-independence, with major progress only after India joined the WHO's Program for International Drug Monitoring in 1997. The National Pharmacovigilance program launched in 2005 eventually advanced into the Pharmacovigilance Program of India (PvPI) in 2010, now coordinated by the Indian Pharmacopoeia Commission (IPC).[9]	Japan's regulatory transformation began after the thalidomide disaster of the 1960s. It established the Drug Side Effect Relief System in 1961 and progressively formalized its approach with the Pharmaceutical Affairs Law (PAL),[9] later amended to the Pharmaceutical and Medical Devices Act (PMD Act). The PMDA, created in 2004, manages drug approvals, PMS, and ADR monitoring

Methodology

This comparative review surveys official regulatory documents, academic literature, and WHO/ICH guidelines. It compares pharmacovigilance systems based on the following dimensions:

- Regulatory authority structure
- ADR reporting mechanisms
- Good Pharmacovigilance Practices (GVP)
- Risk management frameworks
- International harmonization practices

Regulatory Framework

India (CDSCO):

The CDSCO oversees drug approval, clinical trial authorization, and PV monitoring in India. Regulatory agreements follow the Common Technical Document (CTD) format, and safety data are reported through Periodic Safety Update Reports (PSURs) and the VigiFlow system. PvPI facilitates ADR reporting via a network of Adverse Drug Reaction Monitoring Centre (AMCs) .[10]The major focus is a critical analysis of regulatory concerns, including guaranteeing product quality and safety and stimulating innovation.

Functions of CDSCO:

- Approval of new drugs and clinical trials
- Import registration and licensing
- Amendment of D and C act and rules
- Banning of drugs and cosmetics
- Testing of new drugs
- Grant of test license, Personal license, NOCs for export
- License approving of blood banks, LVPs, Vaccines, r-DNA products and some medical devices.

- Oversight and market surveillance through inspectorate of center over and above the state authority.

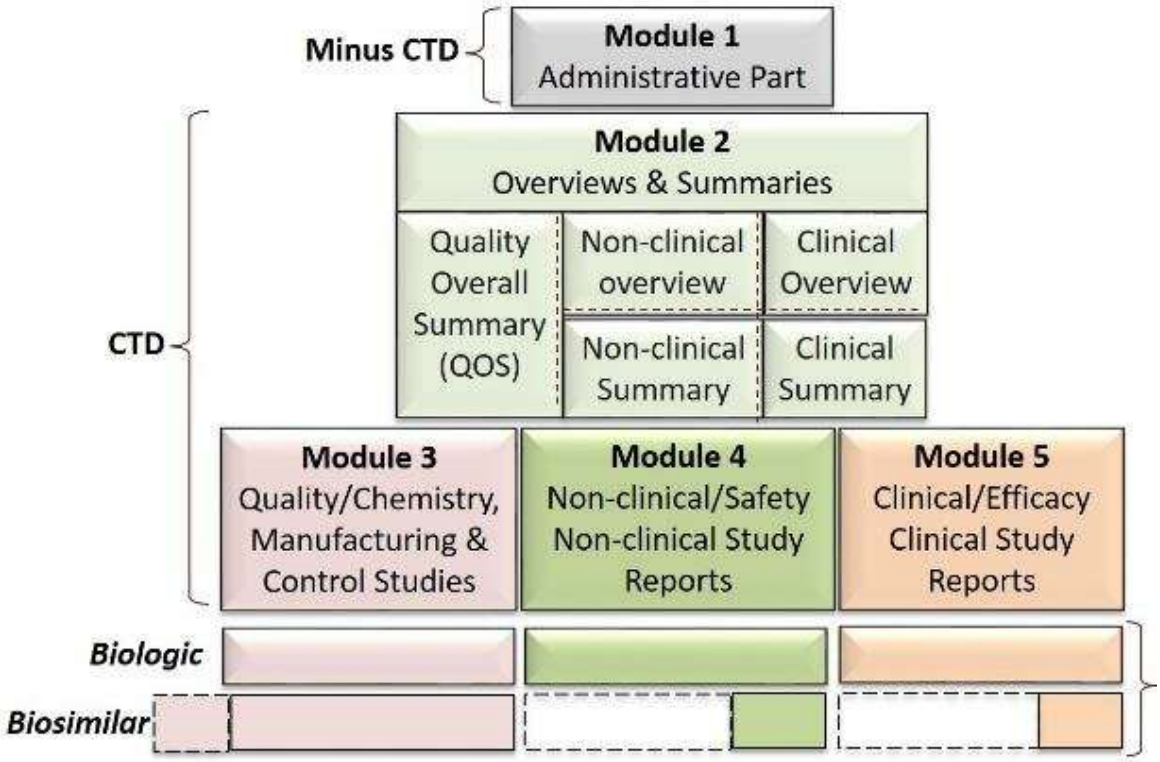

Figure 1: Common Technical Document

Key Features:

- Schedule Y: Legal framework for clinical trials and PV
- Risk Management Plan (RMP) optional unless safety concerns arise
- Spontaneous ADR reporting via forms and mobile applications

Japan:

Japan's regulatory system directs comprehensive PMS through re-examination periods of up to 8–10 years. Pharmaceutical companies must submit RMPs and follow Good Vigilance Practice (GVP) and Good Post-Marketing Surveillance Practice (GPSP).[11]

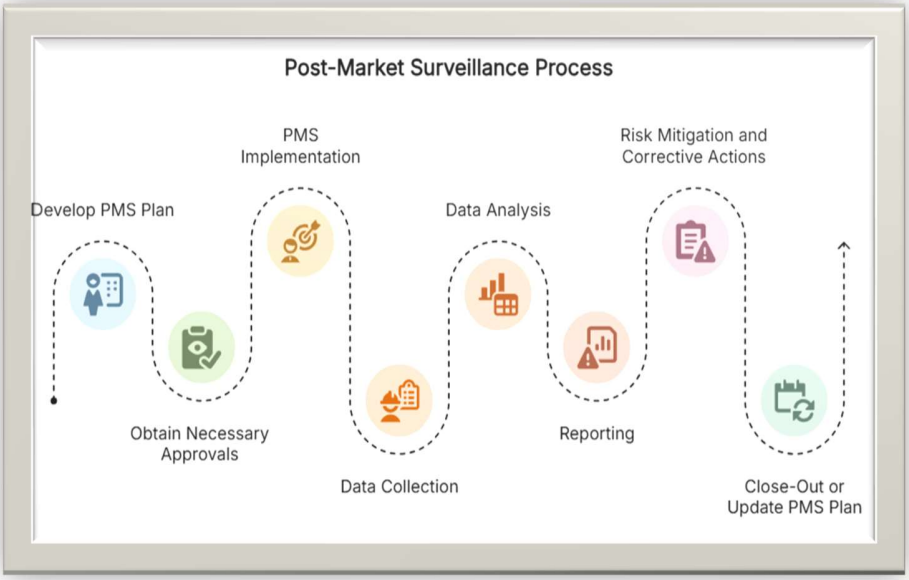

Figure 2: Post-market Surveillance Process

Table:1. GVP Requirements[12]

	Prescription drugs	**Drugs other than prescription ones**	**Quasi drugs, cosmetics**
Organisation and Personnel	A) Creation of Safety Management Department B) Qualified Safety Management Supervisor (Over 3yrs Experience)	A) Not Mandatory B) Safety Management Supervisor (No Qualification Required)	Same as on The Left
SOP etc.	Preparation of SOPs	Same as on The Left	Not Mandatory
Collection of Information for Safety Management	A) Health Care Professionals B) Scientific Papers C)MHLW, PMDA, etc. E) Other Companies F) Others	Same as on The Left	B) and F) are required for Quasi-Drugs and Cosmetics
In-house Inspection, Education/Training	Required	Same as on The Left	Not Mandatory

Key Features:

- Mandatory RMPs for all new drugs
- Re-examination system post-approval
- Japanese Adverse Drug Event Report (JADER) database

- Early Post-Marketing Phase Vigilance (EPPV) system

ADR Reporting system

Table 2. ADR Reporting system

Feature	India	Japan
Central Database	Vigiflow (WHO)	JADER (PMDA)
Public Reporting	Yes, via forms and helplines	Limited, but expanding
Timelines	SUSARs within 15 days	Serious ADRs within 15 days
Rick-Based Prioritization	Moderate	High (re-examination. EPPV)

India's system relies heavily on voluntary spontaneous reports, whereas Japan enforces mandatory reporting and prioritizes surveillance for high-risk products through EPPV.[13]

Risk management Systems

India:

India established formal risk management guidance through CDSCO's Good Pharmacovigilance Practices (2018). Marketing Authorization Holders (MAHs) must submit PSURs biannually for the first 2 years and annually thereafter. A Qualified Person for Pharmacovigilance in India (QPPVI) is required.

Risk management in pharmacovigilance is crucial for the safe administration of medications and the protection of patient health. Risk detection, risk assessment, risk minimization, and risk communication are the four processes in managing a single risk. A typical pharmaceutical product will have varying hazards in terms of their severity, how they impact specific patients, and how they impact the health of individuals and society as a whole. Combining data on several risks should therefore be taken into account when considering risk management to ensure that, for both the patient and the public at large, the benefits outweigh the risks by as large a margin as is practical.

Due to the benefit-risk ratio, several medications are prohibited in India. Metamizole is what they are. This substance is a nonsteroidal anti-inflammatory. In India, methazole was outlawed in 2013. Bone marrow depression is a side effect. it lowers blood cell production.[14]

WHAT IS IMPORTANT IN RISK MANAGEMENT:

Risk detection Risk minimization

Risk assessment Risk communication

Japan:

PMDA's Risk Management Plan system commands detailed safety profiling and post-approval studies. All-case surveillance is often required for biologics and oncology drugs, enabling systematic data collection on adverse effects in all treated patients.[15]

Risk management Options in Japan:

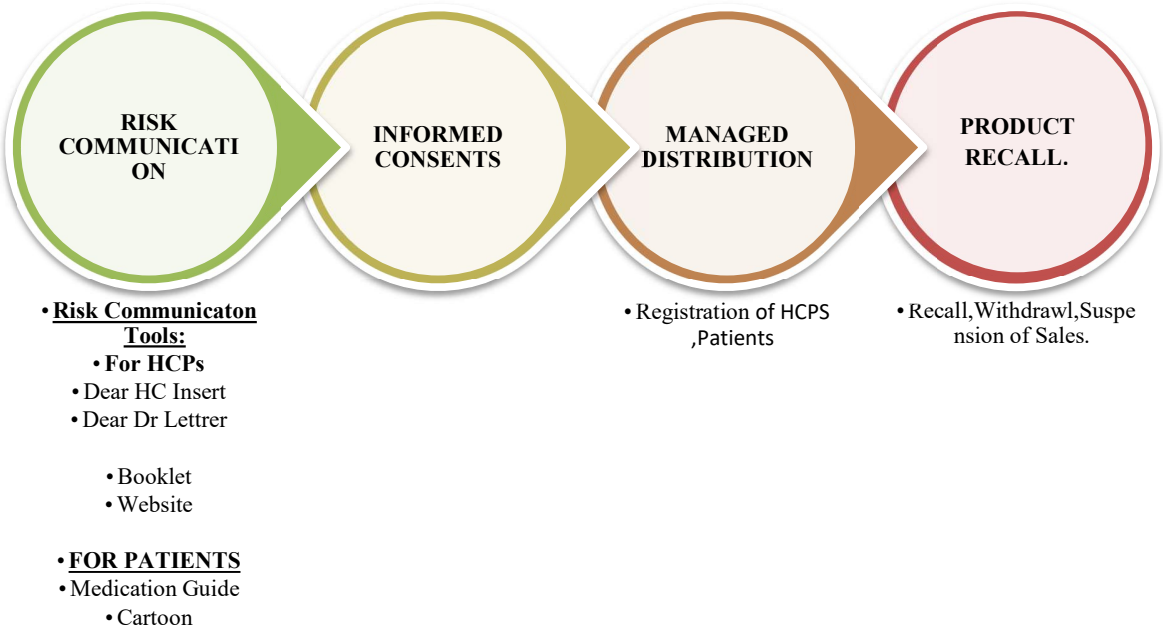

Figure 3: Risk Management Options in Japan

DISCUSSION

This qualified study highlights structural and procedural differences in pharmacovigilance between India and Japan:

- ADR Reporting: India's PvPI system is expanding, yet faces underreporting and inconsistent awareness. Japan's EPPV and mandatory systems create higher compliance and earlier signal detection.
- Risk Management: Japan's RMP and re-examination mandates are stricter than India's flexible frame work. However, Japan's strict protocols may burden sponsors.
- International Harmonization: Both countries align with ICH guidelines (E2E, E2C, etc.), but Japan's implementation is more rigorous.

Challenges in India:

The main challenge is underreporting of ADRs, caused by lack of expertise, shortage of skilled PV staff, poor awareness, outdated infrastructure, delays between guidelines and laws, conservative attitudes, and minimal inspections.

Leveraging India's strong IT sector, PV experts should work with software professionals to build robust ADR reporting and analysis systems for tracking drug utilization trends, compliance, errors, and interactions.[16]

With rising clinical research and PV outsourcing in India, the DCGI must invest in strong PV infrastructure, enabling independent regulatory decisions.

Unrecognized ADRs can cause patient deaths and impose heavy financial costs. The risk increases when new drugs are launched without long-term safety studies and patients self-medicate or switch from POM to OTC.

As Indian companies expand R&D, continuous monitoring after product launch is vital. DCGI should mandate PV activities and establish a culture of regular inspections to determine safe drug use.

Underreporting due to low awareness

- Fragmented infrastructure
- Limited integration of IT tools[16]

Challenges in Japan:

Pharmacovigilance (PV) in Japan faces several interlinked challenges shaped by demographic trends, healthcare practices, and regulatory structures. The country's rapidly ageing population contributes to high rates of polypharmacy, increasing the likelihood of adverse drug reactions (ADRs) and drug–drug interactions, while making it difficult to distinguish ADRs from age-related health issues. Multiple specialists often treat the same patient, complicating consistent monitoring and reporting of ADRs. [17]Although Japan's Pharmaceuticals and Medical Devices Agency (PMDA) has a robust system, timely ADR reporting remains a challenge due to complex processes, under-reporting by healthcare professionals, and uncertainty over causality. Language barriers slow the integration of international safety information, as global PV data often requires translation before regulatory action. Post-marketing surveillance (PMS), largely conducted by manufacturers, can be limited in scope, missing rare ADRs. The rise of drug–device combination products and Japan's Sakigake fast-track approval system introduce additional monitoring complexity, as innovative therapies may enter the market with less pre-approval safety data, placing greater significance on post-market PV. Cultural norms, such as patients' reluctance to question physicians, hinder direct patient ADR reporting, while fragmented healthcare data systems limit real-time safety monitoring. Together, these factors create a PV environment that demands stronger patient engagement, enhanced data integration, and greater regulatory capacity to manage growing volumes of safety data.

- Heavy regulatory burden on sponsors
- engagement in ADR reporting still limited

Recommendations:

To strengthen pharmacovigilance, India should:

- Mandate RMPs for all new drugs, as Japan does.
- Enhance public awareness and training programs.
- Integrate real-world evidence and electronic health records.
- Expand PvPI outreach and incentives for reporting.

Japan, in turn, could:

- Streamline compliance processes for small and medium enterprises.
- Promote direct consumer ADR reporting.
- Both nations should further harmonize with global systems and share data to boost regional pharmacovigilance.

THE ROLE OF PHARMACOVIGILANCE AND CURRENT DEVELOPMENT IN INDIA AS COMPARISON WITH JAPAN

Table 3: The Role of Pharmacovigilance and current development in India as comparison with Japan

Parameters	India	Japan
Origin of pharmacovigilance	Started formally in 2004 with the launch of the National Pharmacovigilance Program, evolved into PVPI in 2010.	Triggered by the Thalidomide tragedy in the 1960s introduced a relief system in 1961.
Regulatory authority	Central drugs standard control organization (CDSCO) under ministry of Health and family welfare.	Pharmaceuticals and medical devices agency (PMDA)under ministry of Health, Labor and Welfare (MHLW).
Recent Development (2024-2025)	Updated trial guidelines, digital PV tools, licensing for medical devices, stronger regulatory oversight	Integration of big data, rapid COVID-19 vaccine surveillance, stronger EPPV enforcement.
Risk management plans (RMPs)	RMPs required for new drug applications; CDSCO guidelines issued in 2017.	Mandatory for all new drugs since 2014.
Regulatory Framework	Schedule Y of Drugs and Cosmetics Rules (1945), amended 2005; GVP (2018).	Pharmaceutical and Medical Device Act (PMD Act); GVP & GPSP guidelines.
Digital Tools	VigiFlow, SUGAM portal for submission, e-reporting.	JADER, EPPV (Early Post-Marketing Phase Vigilance), digital PMS systems, RWE use.
Public Involvement	Citizens can report ADRs via helpline, online form, or AMC center	Yellow Card system allows direct reporting by consumers; DHPLs issued to healthcare providers.
Challenges	Underreporting, lack of awareness, insufficient infrastructure, limited real-world data use.	High regulatory burden, costly all-case surveillance, low public ADR awareness.

Future Prospective	Strengthening training, improving IT infrastructure, national ADR culture promotion	More real-time surveillance, better integration of big data analytics, enhanced transparency and consumer engagement.

CONCLUSION:

Pharmacovigilance is median to public health and requires a well-coordinated regulatory system. India and Japan, despite their contrasting approaches, have built robust frameworks to guarantee drug safety. India's PVPI is growing but must overcome infrastructural and awareness barriers. Japan's mature PV system emphasizes structured PMS and data-driven risk management.

This comparative analysis recommends the integrating of best practices India's growing digital tools and Japan's rigorous post-marketing systems could lead the way to more comprehensive and globally harmonized pharmacovigilance frameworks.

Conflict of interest/financial disclosures:

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

REFERENCES

1. Jyoti B. Gadhade, Rajesh S. Hiray, Rekha Y. Aherkar, Kalpana U. Shah Pharmacovigilance programme of India: revival of the renaissance. International Journal of Basic Clinical Pharmacology. November 2018 ;7(11) :2281-2285.
2. Evangeline L, Mounica NVN, Sharmila Reddy V, Ngabhushanam MV, Nagarjuna Reddy D and Brahmaiah Bonthagarala. Regulatory process and ethics for clinical trials in India (CDSCO). The Pharma Innovation Journal. 2017;6(4):165-169.
3. Yadong Wang, Yue Chen, Xingjuan Xu, Ting Ying, Runan Xia, Yuanyuan Zhang, Xuefeng XIE. What Affects the Quality of Pharmacovigilance? Insights from Qualitative Comparative Analysis. Pharmacology Research and Perspectives. May 8 2025;13(3): e70102.
4. Gorle Harika, Malleswari B, Mounika U, Ch Babu Rao. Regulatory Affairs and Regulatory Requirements for New Drug Approval. Journal of Modern Techniques in Biology and Allied Sciences., 2025:2(1)32–37.
5. Malak M. Khalifeh, Nicholas D. Moore, Pascale R. Salameh. Self-medications with potential abuse in the Middle East: a systematic literature review. International Journal of Basic Clinical Pharmacology. 2016; 5(6).

6. Muhammad Akhtar Abbas Khan, Saima Hamid and Zaheer-Ud-Din Babar. Pharmacovigilance in High-Income Countries: Current Developments and a Review of Literature. Pharmacy Jan 6 2023;11(1):10.
7. Jayant Kumar, Ajmera Ramkishan, Madhugiri Prakash Venkatesh. Bridging the Gap: Aligning GMP Requirements for Generic Manufacturing across the US, EU and Japan. International Journal of Pharmaceutical Investigation, Vol 13, Issue 3, Jul-Sep, 2023
8. Junichi Asano, Hiromi Sugano, Hiroyuki Murakami, Atsushi Noguchi, Yuki Ando and Yoshiaki Uyama. PMDA Perspective on Use of Real-World Data and Real-World Data Evidence as an External Control: Recent Examples and Considerations. Clinical Pharmacology & Therapeutics. Jan 3 2025, Vol 117(4):910-919.
9. Jian Yang and Fan Li. The Impact of Technological Progress on Pharmacovigilance| Intech Open [Internet]. Available from: https://www.intechopen.com/chapters/1196670
10. Chimmani Shanthi, B. Ranganayakulu. Development of Innovative Standards for the Registration of Drugs in India Based Upon International Norms. Int J Medicine Pharma Res Vol 13, Issue 1,2025, 4773.
11. Mayuri Rupnawar, Paresh Wani. Pharmaceutical Regulatory Affairs: An Overview of Global Regulatory Frameworks and Emerging Trends. Int J Scientific Res Technology; 2024 1(12), 1-11 .
12. Abdulkader Hayek, Sathvik B Sridhar, Syed Arman Rabbani, Javed Shareef and Tarun Wadhwa. Exploring pharmacovigilance practices and knowledge among healthcare professionals: A cross-sectional multicentre study. SAGE Open Medicine. Volume 12:1-14
13. Ansuman Sahu, Nihar Ranjan Das. ADR Monitoring and Reporting in India. Indian J Pharm Practice. Jul-Sep 2024; Vol 17, Issue 3:198-204.
14. Maheshwari P. Dakhole, Nikita V. Mahalle, Harigopal S. Sawarkar, Neha L. Zod and Umesh R. Bansod. The Impact of Pharmacovigilance On Public Health. World J Pharma Res Vol 13, Issue 21, 2024
15. Teruyuki Honda, Mamoru Narukawa. A Descriptive Comparative Analysis of Safety Concerns Outlaid in the Risk Management Plans of the European Union and Japan - Honda. Pharmacoepidemiology and Drug Safety - Wiley Online Library. Jan 2025: 34(1): e70097.
16. Mai Okuyama, Hajime Kamiya, Satoshi Kamidani, and Akihiko Saitoh. Adverse Event Following Immunization Monitoring System in Japan. The Paediatric Infectious Disease Journal: Feb 1 2024; Volume 43(2): e52-e56.

17. Natsuko Kameyama, Aoi Hosaka and Hideki Maeda. Current Situation and issues regarding termination of risk management plans in Japan. Frontiers in Medicine. 2024,Vol 11: 10.3389/fmed.2024.1387652.