National Stakeholders' Conclave on Materiovigilance and In-Vitro Diagnostics (IVD) Safety

Theme :

Strengthening the Materiovigilance Ecosystem through Multi-Stakeholder Collaboration

3rd September, 2025 (Wednesday)
10:00 am onwards

Advance Level Research Centre
Indian Pharmacopoeia Commission, Ghaziabad

Organized by

Indian Pharmacopoeia Commission

National Coordination Centre - Materiovigilance Programme of India

Ministry of Health and Family Welfare, Government of India

About the Conclave

The **National Stakeholders' Conclave on Materiovigilance and IVD Safety** aims to bring together regulators, manufacturers, quality professionals, and international collaborators to foster a unified approach toward strengthening the materiovigilance ecosystem in India.

The conclave will spotlight key issues such as:

- Regulatory developments under the Medical Devices Rules (MDR), 2017
- Quality control frameworks and standards for IVDs
- Enhancing reporting culture and data-driven decision making
- International alignment through IMDRF and WHO guidance

Special Highlight: Launch of IVD-Specific Adverse Event Reporting Form

In a major step toward improving surveillance of diagnostic products, the conclave will also feature the official launch of a dedicated reporting form for IVD-related adverse events. This form has been designed to streamline and standardize the way laboratories, hospitals, and manufacturers report safety issues with in vitro diagnostic devices. It reflects India's commitment to more precise, timely, and actionable post-market data collection in this rapidly evolving segment.

Why attend ?

- Stay updated on the latest regulatory expectations for medical devices and IVDs
- Learn from global and national experts in materiovigilance
- Explore the launch of the new IVD-specific reporting form
- Participate in open discussions on industry challenges and quality systems
- Contribute to building a robust and responsive vigilance ecosystem

Who should attend ?

- Medical device and IVD manufacturers
- Regulatory and quality assurance experts
- Diagnostic Laboratories
- Healthcare Professionals including clinicians, pharmacists & biomedical engineers

About the IPC

The Indian Pharmacopoeia Commission (IPC) is an autonomous institution under the Ministry of Health & Family Welfare, Government of India, responsible for setting quality standards for medicines. IPC publishes the Indian Pharmacopoeia, develops IP Reference Standards, and promotes regulatory harmonization through global collaboration. It also serves as the National Coordination Centre for both the Pharmacovigilance Programme of India (PvPI) and the Materiovigilance Programme of India (MvPI), supporting post-market surveillance, adverse event reporting, and safety awareness across the healthcare ecosystem.

About MvPI

The Materiovigilance Programme of India (MvPI) was approved by the Ministry of Health and Family Welfare, Government of India, on July 6, 2015, to monitor the safety of medical devices across the country. Since 2018, the Indian Pharmacopoeia Commission (IPC) functions as the National Coordination Centre (NCC) for MvPI.

Key collaborators include:

- SCTIMST, Thiruvananthapuram – National Collaboration Centre
- NHSRC, New Delhi – Technical Support Partner
- CDSCO – Regulatory Partner

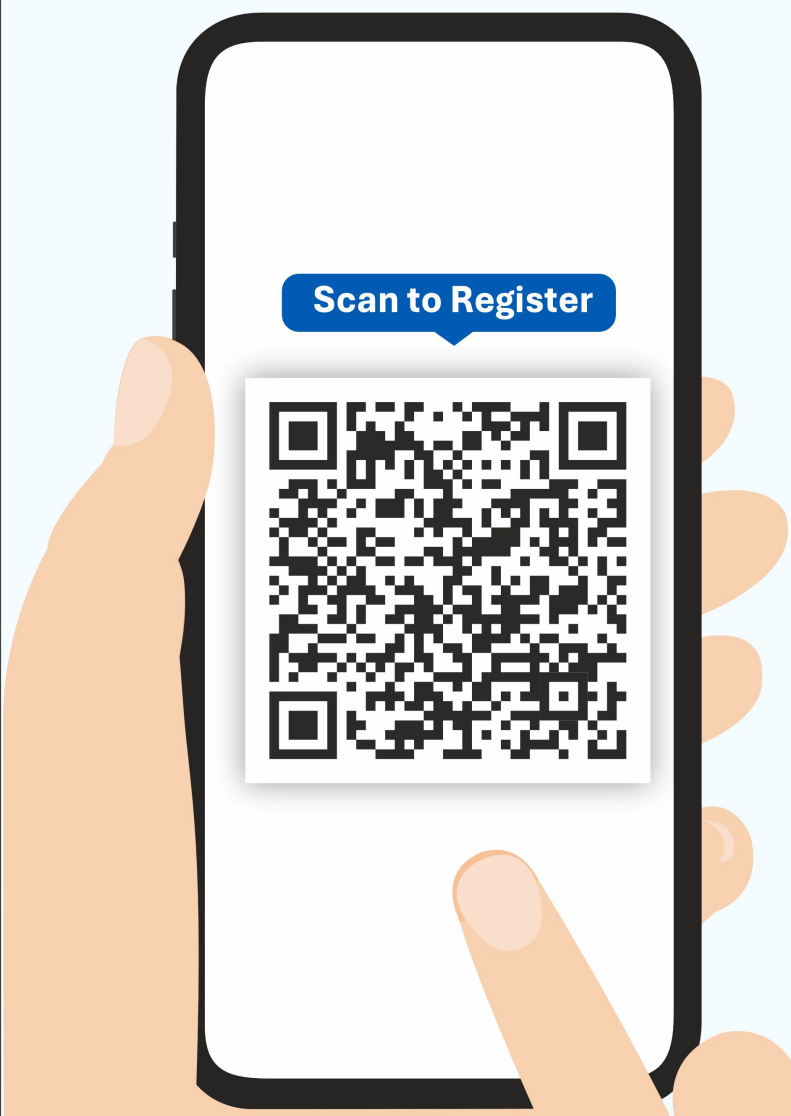
MvPI aims to systematically collect and analyze medical device-associated adverse events (MDAEs) to support evidence-based regulatory decisions. The programme also promotes awareness, evaluates the benefit-risk profile of medical devices, and shares safety recommendations with all key stakeholders.

AGENDA

Time	Session	Speaker / Organization
10:00 AM - 10:10 AM	**Welcome Address**	**Dr. V. Kalaiselvan** *Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Ghaziabad*
10:10 AM - 10:45 AM	**Inaugural Address and Launch of IVD Reporting Form**	To be decided
10:45 AM - 11:00 AM	**TEA BREAK**	
Technical Sessions		
11:00 AM - 11:30 AM	Promoting Patient Safety and Strengthening the Materiovigilance System in India for Quality Devices and Diagnostis	**Dr. Madhur Gupta** *Technical Officer- Pharmaceuticals, WHO India*
11:30 AM - 12:00 PM	Strengthening Medical Device Safety: The Role of ADRMS in Materiovigilance	IPC Representatives
12:00 PM - 12:30 PM	Regulatory Framework for IVD Device Vigilance: Training on the New IVD Reporting Form	CDSCO Representatives
12:30 PM - 01:30 PM	**LUNCH**	
01:30 PM - 02:30 PM	Challenges and Opportunities in Reporting: Industry Perspective	Industry Representatives
02:30 PM - 03:30 PM	Panel Discussion on the Draft Guidance for Hospitals in India for Safety Monitoring and Reporting of Medical Devices related incidents/ adverse events *Reflections by CDSCO, NABH, Patient safety secretariat, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Hospital representatives Open discussion*	IPC/WHO India Moderated by Dr. Madhur Gupta, Technical Officer- Pharmaceuticals, WHO India
03:30 PM - 04:30 PM	Panel Discussion: Enabling a Coordinated Materiovigilance Ecosystem *Reflection by CDSCO, SCTIMST, WHO India, Medical Device Associations, Industry Representatives Open discussion*	**Dr. Bikas Medhi** *Professor,Department of Pharmacology, PGIMER- Moderator*
04:30 PM - 04:45 PM	Closing Remarks	IPC Representative
04:45 PM - 05:00 PM	**HIGH TEA**	

Registration Process

1. Scan QR Code & fill the registration form
2. Pay the registration fee (either QR code/ NEFT/ RTGS) and attach the payment receipt with registration form
3. Review all the details before you submit



How to Register?

For Industry Professionals/ Healthcare Professionals/ Others

Registration Fee:

₹ 2950/- (including 18% GST)

Detail for NEFT/ RTGS:

Name of the Account Holder: Indian Pharmacopoeia Commission

Name of the Bank: ICICI

BankAccount Number: 628601045781

IFSC Code: ICIC0006286

Bank Branch Name: G-2, Patel Nagar III, Ghaziabad, Uttar Pradesh, India

Registration Deadline!!

August 25, 2025

Limited seats available!!
Registration will be accepted based on first come first serve basis.

Certificate will be provided to all registered participants

For any relevant Information/Suggestions/Query

Tel. No. +91-9643460668, 8224889132 Email: shatrunjay.ipc@gov.in, mvpi-ipc@gov.in