सत्यमेव जयते

IPC

e-Newsletter

VOL 7 | ISSUE 1 | 2025

Materiovigilance Programme of India

Published by :
National Coordination Centre - Materiovigilance Programme of India
Indian Pharmacopoeia Commission
Ministry of Health and Family Welfare (MoHFW), Government of India

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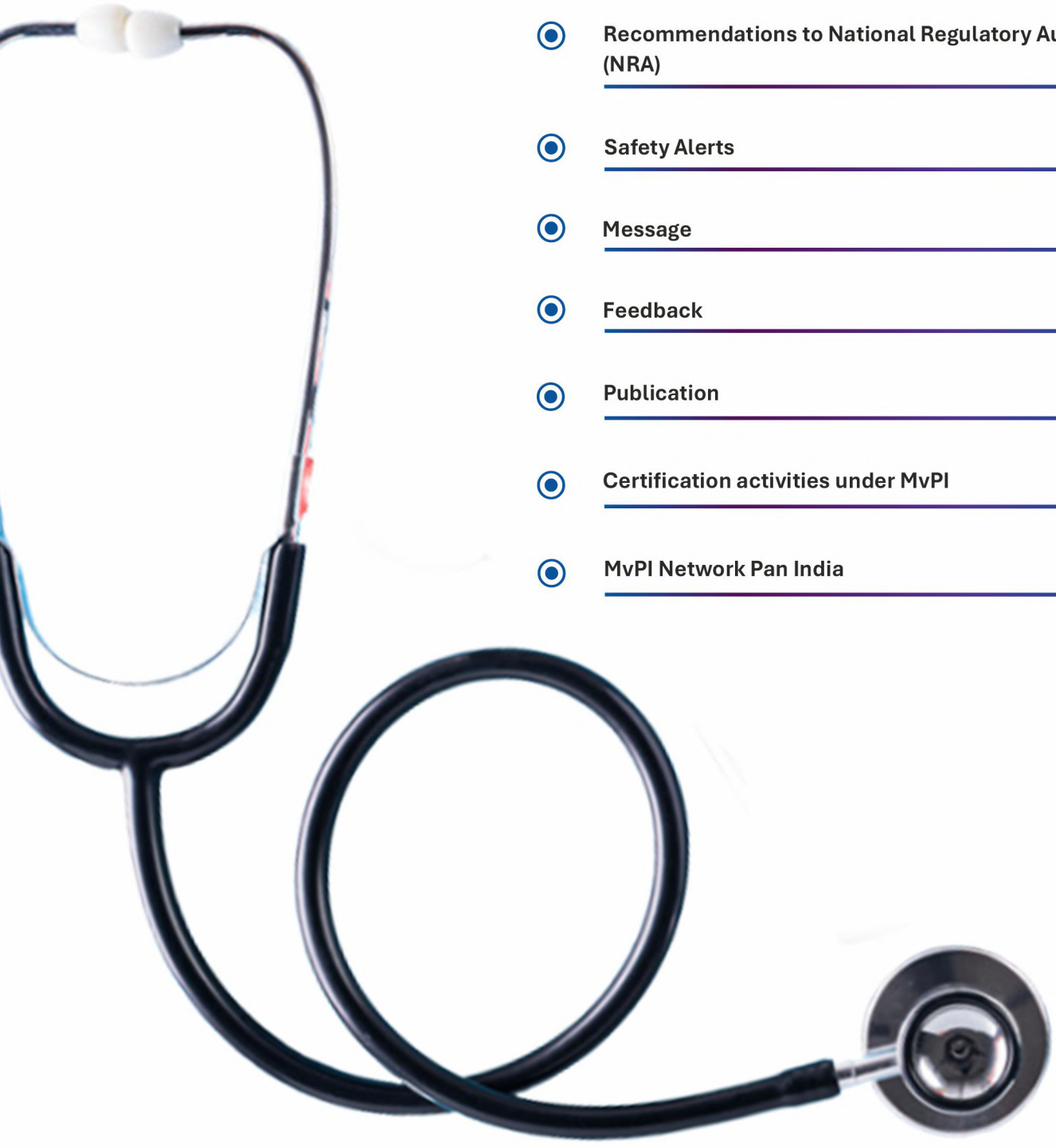


NEWLY APPROVED MEDICAL DEVICE ADVERSE EVENT MONITORING CENTRES (MDMCs) UNDER MvPI

S. No.	State Wise	MDMC Name & Address	Coordinator Name	Functional Department
1.	Andhra Pradesh	GSL Medical College & General Hospital NH-16, Lakshmi Puram, Rajamahendravaram, Andhra Pradesh- 533296	Dr. T. Vidyasagar	Pharmacology
2.	Bihar	Paras HMRI Hospital Bailey Road, Raja Bazar, Patna, Bihar-800014	Mr. Dharmendra Kumar	Biomedical Engineering
3.	Delhi	Venkateshwar Hospital Sector-12 Road, Sector-18A, Dwarka, New Delhi-110075	Dr. Avinash Teli	Clinical Pharmacology
4.		St. Stephen's Hospital Tis Hazari, Delhi-110054	Mr. Lokpal Singh	Biomedical Engineering
5.		Primus Super Speciality Hospital 2, Chandragupta Marg, Opp Russian Embassy, Chanakyapuri, New Delhi, Delhi-110021	Mr. Keshav Kent Lal	Biomedical Engineering
6.	Goa	Manipal Hospital Dr. E. Borges Road, Dona Paula, Panaji, Goa-403004	Sadashiva Acharya	NA
7.	Gujarat	Sunshine Global Hospital Beside Big Bazar, Gaurav Path, Dumas Road, Surat, Gujarat-395007	Mr. Alpesh Ladumor	Biomedical Engineering
8.		Shree Krishna Hospital Bhaikaka University, Karamsad Anand, Gujarat-388325	Mr. Jignesh Sevak	HOD
9.		Smt. Jayaben Mody Multispeciality Hospital Plot No-624/1, Valia Road, GIDC, Ankleshwar, Gujarat-393002	Ms. Maitry Shah	Biomedical Department
10.		All India Institute of Medical Sciences Khanderi, Parapipaliya, Rajkot, Gujarat- 360110	Dr. Rima Shah	Department of Pharmacology

11.	**Haryana**	Sonakshi Children Hospital Jindal Hospital Road, Near ITI, Hisar, Haryana-125001	Dr. Harsh Bhayana	Quality Department
12.		Ojas Hospital H1, Sector-26, Panchkula, Haryana-134116	Mr. Abhishek	Biomedical Engineering
13.	**Himachal Pradesh**	Pandit Jawahar Lal Nehru Government Medical College & Hospital Chamba, Himachal Pradesh-176310	Dr. Aditi Chaturvedi	Pharmacology
14.	**Karnataka**	Justice K. S. Hegde Charitable Hospital Deralakatte, Mangaluru, Karnataka-575018	Mr. Ganesh D Naik	Biomedical Department
15.		Apollo Cradle Hospitals Private Limited 58, 18th Main Road, Near Anand Sweets, KHB Colony, 6th Block, Koramangala, Banglore, Karnataka-560095	Anjitha P.A	Biomedical & Nursing Dapartment
16.	**Kerala**	GG Hospital, (A Unit of Paragon Hospital) Murinjapalam, Medical College, P.O. Thiruvananthapuram, Kerela-695011	Vishnu RG	Director
17.		Sunrise Institute of Medical Sciences Private Limited 37/1835-37, Seaport Airport Road, Kakkanad, Kochi, Kerala-682030	Dr. Amal P.A	Biomedical Department
18.	**Ladakh**	Sonam Nurboo Memorial Hospital Leh Ut Ladakh-194101	Dr. Rinchen Chosdol	NA
19.	**Madhya Pradesh**	Bombay Hospital No.94, IDA Scheme, 95, Eastern Ring Rd, Tulsi Nagar, Vijay Nagar, Indore, Madhya Pradesh-452010	Mr. Dayaram Malviya	Biomedical Department
20.		Bansal Hospital Shahpura C-Sector, Bhopal, Madhya Pradesh-462016	Mr. Chandra Shekhar Sharma	Biomedical Engineering Department
21.		Cancer Hospital & Research Institute Cancer Hills, Gwalior, Madhya Pradesh-474009	Dr. G.S. Rajput	Director
22.		Triveni Healthcare Hospital (A Unit of Jamdar Hospital) Jabalpur, Madhya Pradesh-482002	Mohd. Iftekha Gazi	Quality

23.	**Maharashtra**	HCG Manavata Cancer Centre Mylan Circle, Mumbai Naka, Nashik, Maharashtra-422002	Mr. Sunny Kor	Head of Institute
24.		Sainath Hospital Sant Nagar, Sector-4, Moshi Pradhikaran, Pune Nashik Highway, Maharashtra-412105	Mr. Parag Kulharni	Administrator
25.		Sant Gajanan Maharaj Rural Hospital Site-Chinchewadi, Gadhinglaj-Halkarni Road, Hasurwadi, District Kolhapur, Maharashtra-416503	Dr. Madhav Patade	Pharmacovigilance and Materiovigilance (Radiology)
26.		MGM Hospital & Research Centre Plot No-1, Sector-1A, CBD Belapur, Navi Mumbai, Maharashtra-400614	Ms. Amruta Sadakale	Biomedical Engineering
27.	**Manipur**	American Oncology Institute Cancer Treatment Services Hyderabad Pvt. Ltd. At Babina Speciality Hospital Sajiwa Jail Road, Khabeisoi, Imphal East, Manipur-795010	Salamn Nicky / Mr. David Misong	Biomedical Engineering
28.	**Odisha**	Vikash Multi Speciality Hospital Bargarh, Canal Chowk, Barahagoda, Odisha-768040	Dr. Himanshu Sekar Mishra	Biomedical Engineering Department
29.	**Punjab**	Sacred Heart Hospital Grand Trunk Road, Near Petrol Pump, Maqsudan, Jalandhar, Punjab-144008	Navita Goswani	Biomedical Engineering
30.		Capitol Hospital NH-44, Jalandhar- Pathankot Road, Near Reru Chowk, Jalandhar, Punjab-144012	Dr.(Brig) Avtar Singh Bansal	Medical Administration Including Biomedical Engineering
31.		BBC Heartcare Pruthi Hospital 301, Mahavir Marg, Lajpat Nagar, Jalandhar, Punjab-144003	Rajkumar	Administrator

32.	**Rajasthan**	Apex Hospital Mansarovar Private Limited Ward 27, 55, Rajat Path, Near United Bank of India, Ward 27, Rajat Path, Mansarovar Sector- 5, Mansarovar, Jaipur, R ajasthan-302020	Mr. Rohitash Saini	Anesthesia Department
33.		Apex Hospital Rani Bazar, Bikaner, Rajasthan-334001	Dr. Gurjeet Kaur	ICU
34.		Apex Ranthambore Sevika Hospital Vinayak Nagar, Nursing Board Road, Alanpur, Swm, Rajasthan-322001	Mohd. Ashraf Kagzi	ICU
35.		Harish Hospital Telco Circle, Tijara Road, Alwar, Rajasthan-301001	Jitendra Soni	Biomedical Engineer
36.	**Tamil Nadu**	SRM Global Hospitals Private LimitedMahatma Gandhi Road, SRM Nagar, Potheri, Kattankulathur, Chengalpattu, Tamil Nadu-603203	Dr. Swaminathan Veeraswamy	Biomedical Engineering
37.		Sri Ramakrishna Institute of Paramedical Sciences, College of Pharmacy, Sri Ramakrishna Hospital Campus, 395, Sarojini Naidu, Sidhapudur, Coimbatore, Tamil Nadu- 641044	Dr. V. Saweswaran	Head of Institute
38.		Maa Kauvery (A Unit of Kmc Speciality Hospital Limited) No- 27, Alexandria Road, Cantonment, Tiruchirappalli, Tamil Nadu-620001	Dr. R. Rajesh	Biomedical Engineering
39.	**Telangana**	Ramdevrao Hospital National Highway No. 65, Kukatpally, Hyderabad, Telangana-500072	Dr. N. Yobu	Quality Department
40.		Pranaam Hospitals Private Limited 1-5816/40 & 41, Madinaguda, Miyapur, Hyderabad, Rangareddy District, Telangana-500050	Mr. Ajay Menon	Biomedical Engineering

41.		Basavatarakam Indo- American Cancer Hospital and Research Institute Road No 10, Banjara Hills, Hederabad, Telangana-500034	Mr. S. Ramanjaneya Goud	Administrator
42.		Ankura Hospital For Women & Children (A Unit of Ankura Hospitals LB Nagar Private Limited) Survey No- 9,11,12 Plot No- 10,1/J, Saroor Nagar, Metro Pillar No-1643, Lb Nagar, Ranga Reddy, Telangana-500035	P.Subba Rao	Biomedical Engineerng Department
43.		Medicover Hospitals Opposite. Cyber Gateway, IBIS Hotel Lane Madhapur, Hyderabad, Telangana-500081	Mr. Siva Kumar	Biomedical Engineering Department
44.		Esic- Super Speciality Hospital Sanathnagar, Hyderabad, Telangana-500038	Uppala Satyanarayana	Biomedical Engineering Department
45.	**Uttar Pradesh**	Nazareth Hospital 13/A, Near Hathi Park, Kamla Nehru Road, Prayagraj, Uttar Pradesh-211018	Mr. Akhil Pattnaik	Department of Adminstration
46.		Vinayak Medicare Hospital Bijnor, Lucknow, Uttar Pradesh-226002	Dr Manish Chandra Singh	Biomedical Engineering Dept

Meeting with Biomedical Engineering Colleges

On 07/01/2025, the NCC-MvPI team held a virtual meeting with universities offering Biomedical Engineering (BME) courses to explore potential collaborations. Representatives from DCRUST, Murthal; IIT, Guwahati; Amity University, Haryana; and Mody University, Jaipur participated. During the discussion, NCC-MvPI proposed a minimum 4-month internship for BME students, which was well received by the universities, who expressed their support and willingness to encourage student participation.

13th Induction-cum-Training Programme

On 13/01/2025, the NCC-MvPI team conducted the 13th Induction-cum-Training Programme for 46 newly enrolled MDMCs and 178 MDMCs that received warning letters for inactivity in MvPI.

Meeting with GS1 India

On 23/01/2025, the NCC-PvPI and MvPI teams met with Mr. Bijoy Peter, GM-Technical Services, GS1 India, to discuss potential collaboration. He outlined Gs1 India's role in commerce and how its barcode system could aid in collecting drug and medical device data for PvPI/MvPI reporting forms. The meeting concluded with a request for a demo session to better understand the barcode scanning system.

Materiovigilance CME at RUHS College of Dental Sciences, Jaipur

Materiovigilance CME organized in R.U.H.S. College of Dental Sciences, Jaipur, Rajasthan: A Step towards awareness regarding the use of Medical Devices. Recently, on 29-01-2025, a CME was organized in R.U.H.S. College of Dental Sciences, Jaipur, Rajasthan to promote awareness regarding Materiovigilance Program of India and its importance in Dentistry, in which all the BDS students, Interns, Resident Doctors and Professors participated. The keynote speaker in this CME was Dr. Monica Jain, Additional Principal, SMS Medical College, Jaipur, Rajasthan. The aim of the conference was to bring doctors, medical researchers and students on one platform to raise awareness about the adverse events related to dental materials and its mandatory reporting. Dr. Jaya Sharma, PhD Scholar, SMS Medical College, Jaipur, also evaluated the awareness towards Materiovigilance amongst the participants by sharing with them the questionnaire before the lecture. It was found that there is a great need of sensitization in dental field about Materiovigilance and on how to report the adverse events encountered in their daily practice. In addition, doctors and students shared their experiences of encountering adverse events through practical case studies and theoretical discussions.

CME concluded with an interactive session, in which the participants put their questions before Dr. Monica Jain and discussed the solution of upcoming challenges. The college administration expressed happiness over the success of the event and assured to organize more similar programs in future.

Medtekon 2025 conference

The NCC-MvPI team attended Medtekon 2025, organized by MTaI India on January 30, 2025, at Taj Palace, New Delhi. The conference featured sessions on harmonizing regulatory standards and provided valuable insights into current medtech industry trends.

International Conference on Patient Safety and the 22nd Annual Conference of the Society of Pharmacovigilance

The NCC-MvPI team participated in the International Conference on Patient Safety and the 22nd Annual Conference of the Society of Pharmacovigilance, India, held from February 5-7, 2025, at AIIMS Bhopal. Dr. V. Kalaiselvan, Sr. Principal Scientific Officer, IPC delivered a session on "Medical Devices – Regulations, Quality & Safety Practices in India", while Dr. Shatrunjay Shukla, Scientific Assistant, IPC conducted hands-on training on ADRMS software. Sandeep Mewada (Jr. MvA) actively contributed, enhancing the discussions.

Online Training Programme on Materiovigilance

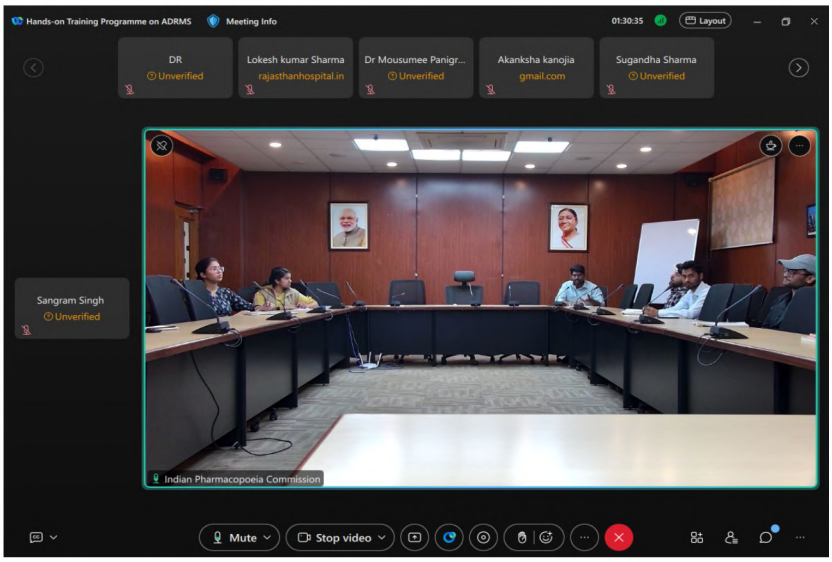
The Online Training Programme on Materiovigilance was conducted on 20th February 2025 at Sir Ganga Ram Kolmet Hospital, New Delhi, organized by the Materiovigilance and Pharmacovigilance Regional Training Centre (North Zone), PGIMER Chandigarh, under the guidance of Prof. Bikash Medhi. The program aimed to enhance awareness of Materiovigilance (MvPI) by emphasizing the identification, reporting, and analysis of medical device-related adverse events to ensure patient safety. IPC functions as the National Coordination Centre (NCC), and CDSCO acts as the regulator, with efforts to encourage voluntary reporting, expand vigilance to all healthcare systems, and implement mandatory reporting for manufacturers and healthcare providers. With 21 participants, including faculty members, hospital residents, and students, the program featured key lectures by Prof. Bikash Medhi on Materiovigilance and Causality Assessment of Medical Devices and Mr. Abhishek on ADRMS (Adverse Drug Reaction Monitoring System). The event concluded with an interactive session, stressing the significance of adverse event reporting, the role of healthcare professionals and patients, and the need for continued education and awareness programs to enhance patient safety and rational medical device use.

24th Residential Training Programme on "Good Clinical Practices and Pharmacovigilance" on February 22, 2025 at NIHFW, Munirka, New Delhi.

The NCC-MvPI team participated in the 24th Residential Training Programme on "Good Clinical Practices and Pharmacovigilance" on February 22, 2025, conducted by CDSCO at NIHFW, Munirka, New Delhi. Mr. Naveen V., Scientific Assistant, delivered a session on the "Overview of Materiovigilance System in India," highlighting its framework and the role of regulators. The training aimed to equip CDSCO and State Drug Inspectors with updates on Schedule M, GCP, and Pharmacovigilance

Hands-on Training Programme on ADRMS

The NCC-MvPI team conducted a Hands-on Training Programme on ADRMS on February 25, 2025, at IPC, Ghaziabad, with 219 participants. Dr. V. Kalaiselvan introduced the Materiovigilance Programme of India, emphasizing adverse events monitoring.



Training sessions included:

- Ms. Numra Saifi (Jr. MvA): ADRMS registration process
- Mr. Amol (Jr. MvA): Reporting adverse events in ADRMS

The training led to 8 new ADRMS registrations and 34 reports submitted, strengthening healthcare professionals engagement in adverse event reporting.

Materiovigilance Sensitization Program conducted at Rajagiri Hospital.

The Materiovigilance Sensitization Program on the topic "Enhancing Patient Safety through Materiovigilance" was successfully conducted on March 15, 2025, at Rajagiri Hospital, by Al Shifa College of Pharmacy in collaboration with Indian Pharmacopoeia Commission (IPC, MVPI). A total of 160 healthcare professionals including doctors, nurses, pharmacists, biomedical engineers and hospital quality professional attended the program. Dr. Pallavi P. (Assistant Professor, Department of Pharmacy Practice & PhD Scholar in Materiovigilance at KUHS (Kerala University of Health Sciences) presented a session on "Introduction to Materiovigilance". She introduced the participants to the concept of Materiovigilance, its significance in clinical settings, and the need for a structured reporting system. Ms. Numra Saifi – Jr. Materiovigilance Associate, MvPI, IPC also delivered the session regarding "Effective Materiovigilance Reporting: Navigating (ADRMs) for Patient Safety provided an in-depth session on effective reporting of adverse device reactions (ADRs). She emphasized the role of healthcare professionals in detecting and documenting medical device failures.

Continuous Medical Education (CME) on Patient Safety Week

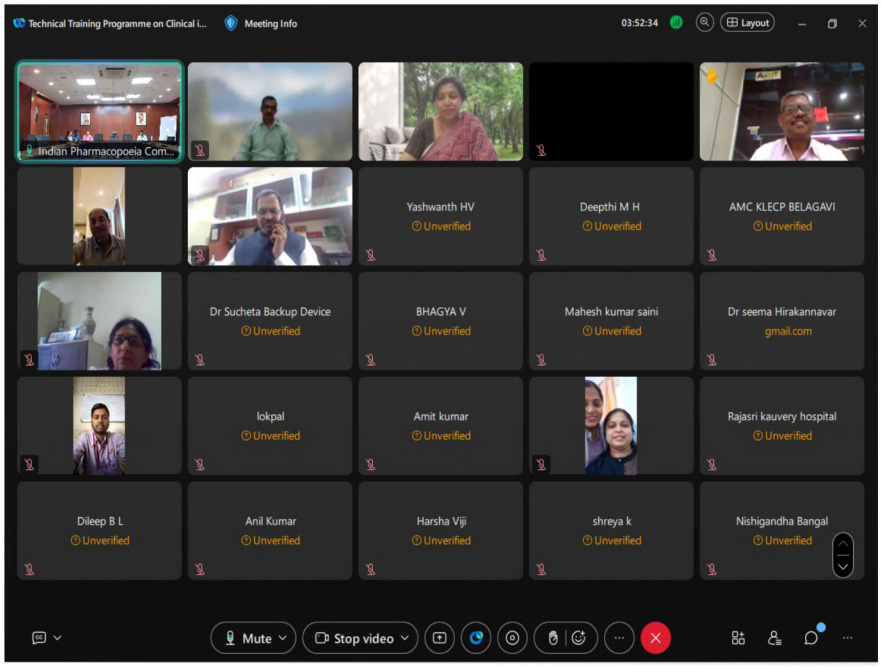
The Continuous Medical Education (CME) on Patient Safety Week was organized by the Department of Pharmacology, PGIMER, Chandigarh, on 20th–21st March 2025 at Nine Auditorium, PGIMER. The event was inaugurated by Prof. Bikash Medhi and Dr. Ajay Prakash, emphasizing the significance of pharmacovigilance and materiovigilance in ensuring patient safety. With 250 participants, including medical professionals, students, and researchers, the sessions provided key insights into global and national perspectives on patient safety, adverse event reporting, and regulatory frameworks.

On 20th March 2025, Prof. Bikash Medhi delivered a lecture on "Role of Patient Safety from Pharmacovigilance and Materiovigilance: A New Era", discussing the evolving role of vigilance systems in identifying and preventing ADRs and medical device-related issues. He highlighted regulatory frameworks, technological advancements, and real-world case studies demonstrating the impact of vigilance in improving healthcare safety.

On 21st March 2025, Dr. Ajay Prakash presented a lecture on "Global Prospective of Pharmacovigilance and Materiovigilance", exploring international standards, regulatory challenges, and the importance of global collaboration. He emphasized the role of AI, data sharing, and harmonization of safety practices across different countries.

The interactive discussions engaged participants in understanding practical applications and emerging technologies in patient safety. The event concluded with key recommendations, including the need for continuous training, further research on new technologies, and fostering institutional collaborations to enhance global patient safety initiatives.

Technical Training Programme on Clinical investigation of Medical Devices by IPC & KAHER



The Technical Training Programme on Clinical Investigation of Medical Devices (March 26, 2025) by IPC & KAHER covered key regulatory, clinical, and safety aspects. Dr. V. Kalaiselvan & Dr. M. S. Ganachari highlighted the role of materiovigilance and pharmacists in device safety. Mr. V. Naveen, Scientific Assistant presented India's medical device safety surveillance framework. Mr. Somnath Basu explained MDR 2017 regulations, CDSCO's role, and clinical investigation requirements. Dr. Gananjay Salve discussed challenges in cardiac surgery device trials, including valve durability. Dr. Geetanjali Shalimath emphasized AE/SAE reporting, ethics, and regulatory compliance. Dr. Sucheta Banerjee Kurundkar covered ISO 14155:2020 and Good Clinical Practice (GCP) in device investigations. Dr. Rajesh Sharma addressed IVD performance evaluation and biological testing standards. The session concluded with a Q&A and closing remarks from IPC & KAHER.

Materiovigilance Expert Committee Meeting Report at KIMS Al Shifa Hospital

The Materiovigilance Expert Committee Meeting at KIMS Al Shifa Hospital on March 27, 2025, focused on strengthening medical device safety monitoring and improving adverse event (MDAE) reporting. Key discussions included challenges in MDAE reporting, root cause analysis of device-related incidents, and strategies for enhancing awareness and training. Identified issues involved ECG leads causing allergic reactions, infusion pumps with flow inconsistencies, orthopaedic implants linked to complications, faulty urine pregnancy test kits, and catheter-related infections. Recommendations emphasized structured training, quality checks, and streamlined reporting. Collaboration with regulatory authorities, including MvPI, was discussed, alongside the integration of materiovigilance into routine hospital practices. The committee decided on quarterly meetings to ensure continuous improvement. Notable achievements included the inauguration of an AMC, research publications, awards for poster presentations, and the release of materiovigilance guidelines. The meeting concluded with commitments to enhance reporting compliance, conduct regular training, and strengthen regulatory collaborations for improved patient safety.

Materiovigilance Awareness Activity at MCSRC, Patna

A Materiovigilance Awareness Activity was successfully conducted on March 28, 2025, at Mahavir Cancer Sansthan and Research Centre (MCSRC), Patna, under IPC-Regional Training Centre (RTC), NIPER Hajipur, to educate healthcare professionals on medical device adverse event reporting under MvPI. The event was graced by senior dignitaries, including Dr. Sanyal (Director, MCSRC), Dr. Manisha Singh (Medical Director), and Dr. Vinita Trivedi (Head, Radiation Oncology), demonstrating institutional commitment to patient safety. Dr. Sameer Dhingra (NIPER Hajipur, AMC Coordinator) introduced the session, highlighting the growing role of materiovigilance in India. Dr. Shatrunjaya Shukla (Scientific Assistant, IPC, Ghaziabad) provided an insightful overview of MvPI's role in monitoring adverse events, encouraging proactive reporting. Dr. Krishna Murti (Deputy Coordinator, MvPI-RTC, NIPER Hajipur) conducted a practical demonstration on filling the Medical Device Adverse Event Reporting Form, followed by an interactive Q&A session addressing reporting timelines, compliance, and quality management. The event concluded with a Vote of Thanks by Dr. Richa Chauhan (Senior Consultant, Radiation Oncology, MCSRC), acknowledging IPC Ghaziabad and NIPER Hajipur for their support. Token of appreciation was presented to key speakers. The session successfully strengthened materiovigilance awareness, reinforced MCSRC's commitment to patient safety, and laid the foundation for future training initiatives in medical device vigilance.

Upcoming MvPI Events 2025

Stay updated with key trainings and workshops aimed at enhancing medical device safety across India.

Join us in shaping the future of medical device safety!

Event	Venue	Tentative Dates	Focus Area
Workshop on Materiovigilance Program of India (MvPI) for Promoting Safety of Medical Devices	Seminar Hall, Auditorium, AIIMS, Gorakhpur	22nd April 2025	Regulatory Insights and MDAE detection, assessment and Reporting
Materiovigilance: Opportunities & Challenges	National Institute of Pharmaceutical Education and Research (NIPER), Bihar	25th April 2025	Exploring Future Prospects
RTC Training	Jawaharlal Nehru Medical College (JNMC), UP	25th May 2025	Strengthening Materiovigilance Practices
Medical Device Safety & Risk Management	National Institute of Pharmaceutical Education and Research (NIPER), Bihar	27th June 2025	Ensuring Safer Healthcare Practices

Stay engaged with MvPI's expert-led workshops and trainings !

Internship at Materiovigilance Programme of India

MvPI E-Poster Competition

Celebrating Innovation and Excellence

We are thrilled to announce the incredible success of our E-Poster Competition on Materiovigilance, held in March 2025 as part of our Materiovigilance Internship Program!

The competition witnessed remarkable enthusiasm and creativity from our interns, who showcased innovative ideas, cutting-edge research, and best practices in the field of medical device safety. Their dedication and passion for enhancing patient safety truly stood out!

A huge congratulations to our winners!

- Akanksha Kanojia (AIIMS, Gorakhpur) – 1st Place
- Shubham Choubey (IPC, Ghaziabad) – 2nd Place

Both winners impressed the panel with their insightful and impactful posters, setting new benchmarks in Materiovigilance awareness!

Stay tuned as we showcase the winning posters and share key takeaways from this exciting and inspiring event in this edition of our newsletter.

Enrollment as Medical Device Adverse Event Monitoring Centre under MvPI

RECOMMENDATIONS TO NATIONAL REGULATORY AUTHORITY (NRA)

NCC-MvPI sent a recommendation to CDSCO on **"Blister Formation, Blue & Hypopigmented Patch at the Insertion Site, Leakage Through Cannula during Drug Administration, Suboptimal/Low Quality Stylet, Stylet & Catheter Wings Stucking Together"** associated with **"Intravenous Cannula"** for information and necessary actions at their ends.

NCC-MvPI sent a recommendation to CDSCO on **"Allergic Reactions (Redness, Drying, Itching), Poor Quality, (Tearing of Gloves During Medical Examination), Excessive Absorption of Powder on Hands"** associated with **"Rubber Surgical Gloves"** for information and necessary actions at their ends.

NCC-MvPI, IPC has observed an adverse event report of **"Quality issues like plunger breakage, blockage. Leakage, presence of foreign particles" associated with the use of "Auto-Disable Hypodermic Syringe"** which may lead to serious adverse event.

S. No.	Suspected Device Details	Event Details
	Device Name	
1.	Auto-Disable Hypodermic Syringe	Quality issues like plunger breakage, blockage. leakage, presence of foreign particles

NOTE

You are requested to closely monitor the adverse events of these devices at your respective monitoring centre. If these devices are being used at your hospital, kindly report all the suspected adverse events related to above mentioned medical devices, if any, using the reporting form, available on www.ipc.gov.in and send via e-mail to: mvpi.ipc@gov.in & shatrunjay.ipc@gov.in

Message

The content of this safety alert is highly confidential. It is strictly forbidden to share any part of the message with any third party/vendor or on public platforms such as social media, local newspapers/posters etc., without the written consent of the publisher. Your support in this regard is highly solicited.

Your support in this regard is highly solicited.

MESSAGE

Dr. Harmeet Singh Rehan
Director-Professor and Head Department of Pharmacology, Lady Hardinge Medical College, New Delhi

The inception of the Materiovigilance Program of India (MvPI) aims to monitor the safety and effectiveness of medical devices and materials throughout their lifecycle. This includes everything from the initial design and manufacturing stages to their use in clinical settings and eventual disposal. In today's healthcare environment, where medical devices play a crucial role in diagnosis, treatment, and patient care, ensuring their safety and efficacy is paramount. I would like to highlight that materiovigilance has become an essential aspect of our healthcare system and has significantly impacted patient safety and the overall quality of healthcare delivery.

Protecting patients from harm caused by defective or unsafe medical devices is the primary goal of MvPI. The monitoring of adverse events and incidents has successfully identified several potential risks associated with medical devices and implemented measures to mitigate them. The effective regulatory compliance of MvPI with national and international regulations is immense, ensuring that medical devices meet required safety standards and fostering public confidence in healthcare providers and regulators. The collection and analysis of post-market data on adverse events have allowed for the identification of trends and patterns that can inform improvements in design, manufacturing, and usage protocols, guiding regulatory actions such as recalls or safety warnings. This continuous feedback loop is vital for enhancing the safety and effectiveness of medical devices.

I appreciate the efforts of MvPI in fostering awareness among healthcare professionals about the importance of reporting adverse events, recognizing potential device-related complications, and understanding the need for vigilance in patient care. As we advance further into an era of innovative medical technology, our commitment to materiovigilance becomes increasingly critical. I extend my heartfelt appreciation for the exceptional leadership of MvPI in successfully implementing the program across the country. The importance of monitoring the safety and effectiveness of medical devices cannot be overstated, and the commitment to establishing a robust materiovigilance system has set a benchmark for excellence. Your ability to engage stakeholders, provide training, and promote awareness of the program's objectives has been instrumental in its success.

The positive impact of the materiovigilance program will resonate across the country. With these initiatives, India can significantly enhance the quality of its medical devices, ultimately improving healthcare outcomes and ensuring patient safety. A collaborative approach involving government, industry, academia, and healthcare providers is essential to drive these changes effectively.

Feedback on MvPI

It has been a great privilege to work as an intern at MvPI, where I gained hands-on experience with the MDAE reporting form and ADRMS software. MvPI is vital in ensuring public health safety by preventing adverse events related to medical devices. I believe greater awareness of MvPI is needed among stakeholders across India. Furthermore, stronger collaboration between IPC, SCTIMST, NHSRC, and CDSCO is essential for timely regulatory actions. My sincere thanks to the MvPI team for their guidance.

Anushika Kaloo
Ghaziabad
Uttar Pradesh

The Materiovigilance Programme of India (MvPI) is doing great work in keeping medical devices safe and reliable. Its efforts to find and report risks help people trust the healthcare system. However, more people need to know how and where to report problems with medical devices. It would be helpful if individuals who are not healthcare professionals also had clear guidance on how they can report issues easily. Additionally, there is a lack of awareness about MvPI, and the official body should take steps to normalize the term and make it more recognizable to the public. Also, sharing more updates on what actions are taken will build trust. MvPI is very important for public health, and I appreciate the team's hard work in keeping people safe. I am grateful for the opportunity to work in this program and gain valuable knowledge about it.

Shubham Choubey
Nawada
New Delhi

PUBLICATION

NCC-MvPI has published an article entitled “A retrospective study of reported adverse events associated with cardiac stents in Indian population” Expert Review of Medical Devices, 22:2, 149-153, DOI: 10.1080/17434440.2025.2456526

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EXPERT REVIEW OF MEDICAL DEVICES

Expert Review of Medical Devices

ISSN: (Print) (Online) Journal homepage: www.tandfonline.com/journals/ierd20

A retrospective study of reported adverse events associated with cardiac stents in Indian population

Sandeep Mewada, Shatrunajay Shukla, Maneesh Soni, Meenakshi Dahiya, Vivekanandan Kalaiselvan, Pooja Reddy, Avinash Singh Mandloi & Vipin Dhote

To cite this article: Sandeep Mewada, Shatrunajay Shukla, Maneesh Soni, Meenakshi Dahiya, Vivekanandan Kalaiselvan, Pooja Reddy, Avinash Singh Mandloi & Vipin Dhote (22 Jan 2025): A retrospective study of reported adverse events associated with cardiac stents in Indian population, Expert Review of Medical Devices, DOI: 10.1080/17434440.2025.2456526

To link to this article: https://doi.org/10.1080/17434440.2025.2456526

IPC-MvPI as a Certification Body

Indian Pharmacopoeia Commission (IPC) as Certification Body for ICMED 9000/13485 Schemes

IPC is an Autonomous Institution of Ministry of Health and Family Welfare, Government of India.

PRODUCTS & SERVICES

- Periodic publication of Indian Pharmacopoeia
- Periodic publication of National formulary of India
- Preparation & distribution of IP Reference Substances (IPRS) & Impurity Standards
- National Coordination Centre for Materiovigilance Programme of India (MvPI) and Pharmacovigilance Programme of India (PvPI)

ICMED 9000/13485 CERTIFICATION

ICMED (Indian Certification of Medical Devices) is a quality certification scheme, jointly owned by QCI & AIMED for medical device manufacturers in India, ensuring compliance with both Indian regulatory requirements and international standards.

PURPOSE

The purpose of ICMED certification is to ensure that medical devices meet stringent quality and safety requirement mentioned in India MDR & International Standards, thereby enhancing trust and reliability in medical devices being manufactured.

BENEFITS

- Ensure regulatory compliance as per India MDR & International Standards
- Ensure Product Quality
- Enhancing Consumer Confidence
- Better Market Access
- Competitive Advantage

For any query, please contact:

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INDIAN PHARMACOPOEIA COMMISSION
MATERIOVIGILANCE PROGRAMME OF INDIA
Ministry of Health & Family Welfare, Govt. of India
Sector-23, Raj Nagar, Ghaziabad-201002
Email: lab.ipc@gov.in, mvpi-ipc@gov.in Website: www.ipc.gov.in

MvPI Network Pan India

Under the Materiovigilance Programme of India (MvPI), 547 Medical Device Adverse Event Monitoring Centers (MDMCs) have been enrolled; comprising both government and non-government hospitals. The participation of both government and non-government hospitals in MvPI highlights the collaborative effort to uphold medical device safety standards nationwide. These centers play a crucial role in ensuring the safety and efficacy of medical devices used in healthcare settings. By enrolling MDMCs across a wide spectrum of healthcare providers, MvPI aims to comprehensively monitor the performance of medical devices, facilitate early detection of adverse events, and ensure prompt reporting and appropriate action to enhance patient safety and healthcare quality.

Scan QR code to check out the List of MDMCs

www.ipc.gov.in

NCC-PvPI IPC

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Indian Pharmacopoeia Commission

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We have started a journey of Materiovigilance, for saving patient's lives