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Materiovigilance Programme of India

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Contents

Training at S.N.M Hospital, Leh on 06 November 2024

NCC-MvPI in collaboration with SNM Leh hospital Conducted a training programme on “Materiosafe India: A Medical Device Safety Programme for Healthcare Professionals, Help Us to Help You.” The program aimed to enhance medical device quality & safety knowledge among Medical Officers, Technicians, and Staff Nurses at SNM Hospital, attracting a total of 110 healthcare professionals.

This collaboration programme underscored IPC & SNM Hospital’s commitment to fostering a culture of safety and regulatory adherence, empowering its healthcare professionals to provide safer, higher - quality care through diligent monitoring and reporting of medical device - related concerns.

Product Specific Training in Cardiovascular Medical Devices

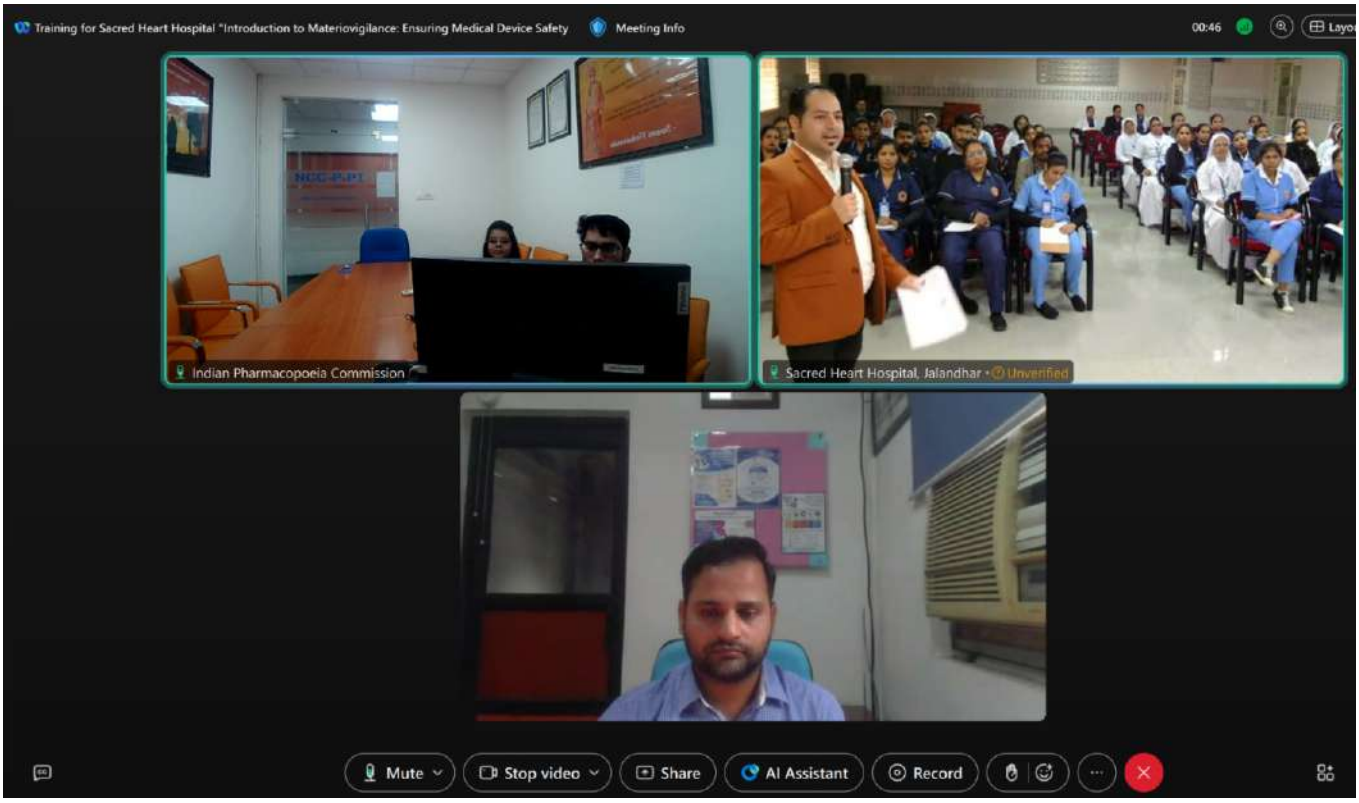
The Materiovigilance Programme of India (MvPI) successfully organized a specialized training program titled "Advancing Knowledge and Practices in Cardiovascular Medical Devices" on 18th November 2024. The session was expertly led by Mr. Hemant Kumar, Senior Manager of Quality & Compliance, Safety & Pharmacovigilance at Syneos Health Pvt. Ltd., India.

This targeted initiative aimed to strengthen participants' knowledge and skills regarding the safe and effective use of cardiovascular medical devices. The program provided a comprehensive overview of critical topics, including best practices, regulatory compliance, and safety protocols. It emphasized the importance of adhering to international and national standards to ensure patient safety and optimize clinical outcomes.

Through this training, participants were equipped with the latest advancements and practical insights to address challenges related to cardiovascular medical devices. By fostering a deeper understanding of regulatory frameworks and quality assurance measures, the program aimed to contribute significantly to enhancing healthcare delivery and device safety in India.

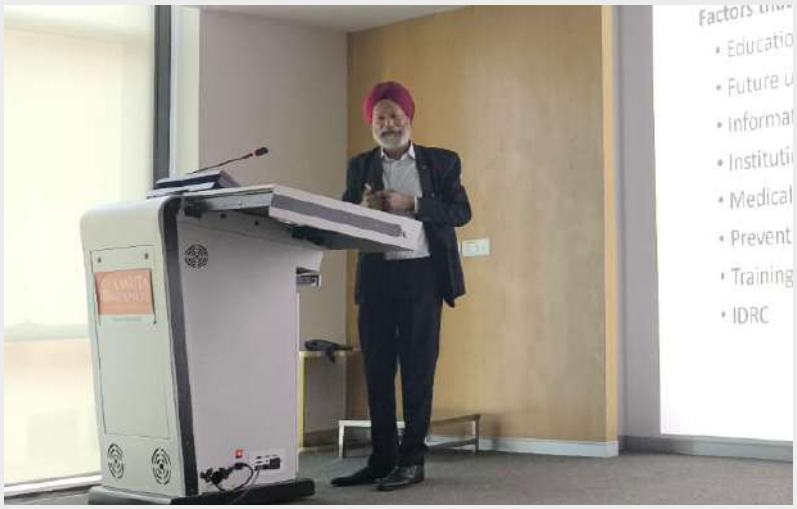
Training at Sacred Heart Hospital, Jalandhar

The NCC-MvPI, in collaboration with Sacred Heart Hospital, Jalandhar conducted a virtual training session on November 22, 2024. The session aimed to familiarize healthcare professionals with the fundamentals of materiovigilance and highlight its critical role in ensuring the safety of medical devices.



Enhancing Medical Device Safety through Collaborative Training at Amrita Hospital, Faridabad

On December 10, 2024, NCC-MvPI collaborated with Amrita Hospital, Faridabad, to conduct a training program titled Enhancing Surveillance and Safety of Medical Devices. The sessions emphasized building capacity in materiovigilance, understanding the MvPI framework, and exploring clinical insights into adverse events associated with medical devices. Experts, including Dr. V. Kalaiselvan, Ms. Shweta Wachaspati, Dr. Harmeet Singh Rehan, and Mr. Naveen V., led discussions on reporting tools and case studies. The program sensitized healthcare professionals at Amrita Hospital to the importance of effective monitoring and reporting for medical device safety.



Guest lecture on “Assessment of Adverse Events Reported for Ophthalmic Medical Devices.”

On December 11, 2024, the Materiovigilance Programme of India (MvPI), under the Indian Pharmacopoeia Commission, Ghaziabad, organized a guest lecture on “Assessment of Adverse Events Reported for Ophthalmic Medical Devices.” The session was conducted by Dr. Girish K. Srivastava, a distinguished Senior Researcher and Principal Investigator at IOBA, University of Valladolid, Spain. Dr. Srivastava shared his expertise on evaluating adverse events and ensuring the safety of ophthalmic medical devices, contributing to advancing knowledge and practices in the field.

ADRMS Training for MDMC Coordinators and Deputies

On December 18, 2024, NCC-MvPI conducted a specialized training program on the Adverse Drug Reaction Management System (ADRMS) for coordinators and deputy coordinators of Medical Device Adverse Event Monitoring Centres (MDMCs). The agenda included an overview of MvPI by Mr. Amol, insights into ADRMS software registration by Ms. Numra Saifi, and a practical demo on reporting in ADRMS by Ms. Krishna. This program effectively enhanced participants' understanding of ADRMS usage, emphasizing its role in streamlining medical device adverse event reporting and strengthening materiovigilance efforts.

Meeting on strengthening IVD related adverse event reporting

On December 27, 2024, the MvPI in collaboration with CDSCO conducted a meeting with the different association members Confederation of Indian Industry (CII), Federation of Indian Chambers of Commerce & Industry (FICCI) and Association of Diagnostics Manufacturers of India (ADMI) to strengthen the reporting system of IVD related adverse events.

Meeting Outcome: Enhancing IVD Reporting and Stakeholder Collaboration

- A dedicated IVD adverse event reporting form will be developed, with the draft submitted to IPC by the stakeholders.
- A yearly awareness program plan for pathology labs on IVD complaint reporting will be prepared.
- ADRMS training sessions will be organized for license holders to enhance reporting practices.
- Region-specific training programs on IVD complaint reporting under PMS will be conducted.

These initiatives aim to advance regulatory efficiency, improve adverse event reporting, and strengthen collaboration across the healthcare sector.

Recommendations to National Regulatory Authority i.e., CDSCO

1. NCC-MvPI sent a recommendation to CDSCO on **"Regulator Malfunctions Causing Free Flowing of Blood, Loosened at the Point of Insertion"** associated with **"Blood Administration set"** for information and necessary actions at their end.

2. NCC-MvPI sent a recommendation to CDSCO on **"Blister Formation, Skin Ulcers, Redness, Leakage, Blockage, Swelling, Irritation, Thrombophlebitis"** associated with **"Intravenous Cannula"** for information and necessary actions at their end.

3. NCC-MvPI sent a recommendation to CDSCO on **"Leakage, Loose Piston, Semi Blocked Plunger, Foreign Particles in Syringe, Vacuum Creation While Loading Medication"** associated with **"Hypodermic Syringe"** for information and necessary actions at their end.

4. NCC-MvPI sent a recommendation to CDSCO on **"Poor Quality, Blockage, Plunger & Piston Breakage, Presence of Foreign Particles"** associated with **"Auto Disposable Hypodermic Syringe"** for information and necessary actions at their end.

Safety Alerts

NCC-MvPI, IPC has observed an adverse event report of Prosthesis Failure & Infection associated with the use of Artificial Urinary Prosthesis which may lead to serious adverse event.

S. No.	Suspected Device Details	Event Details
	Device Name	
1.	Artificial Urinary Prosthesis	Prosthesis Failure & Infection

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 from Senior Biomedical Engineer of Holy Spirit Hospital

The ADRMS software is exceptionally user-friendly and intuitive for reporting MDAEs. Its features and tools are well-structured and perform efficiently, enhancing the overall experience. While I initially faced some technical challenges, with the assistance of Numra Ma'am, all issues were promptly resolved. The platform has significantly contributed to improving the quality of medical device procurement across hospitals and healthcare sectors in India, ensuring greater caution and precision. Most importantly, your efforts are directly helping patients receive the best possible treatment. Thank you very much for your invaluable contributions.

(Bhimashankar)
Executive Director,
Senior Biomedical Engineer
Biomedical Engineering Department
Holy Spirit Hospital, Andheri (E),
Mumbai-400093

Feedback on MvPI

Ayush Giri
Udaipur
Rajasthan

I am grateful to the Indian Pharmacopoeia Commission (IPC) and the Materiovigilance Programme of India (MvPI) for the opportunity to intern and contribute to this significant initiative. This experience deepened my understanding of materiovigilance and its role in patient safety through insightful training, hands-on exposure to the Medical Device Adverse Event (MDAE) reporting system, and exceptional mentorship from IPC and AIIMS Guwahati. Participating in awareness programs highlighted the importance of sensitizing healthcare professionals and the public about MvPI. To improve the program, I suggest making reporting forms more user-friendly with dropdown menus for device categories and enabling follow-up mechanisms for reported events. This internship has been invaluable in enhancing my knowledge and motivating me to contribute actively to healthcare.

Khushi Vishwakarma
Ghaziabad
Uttar Pradesh

I would like to express my heartfelt appreciation for the Materiovigilance Programme of India (MvPI) and its invaluable efforts in ensuring the safety and efficacy of medical devices. By fostering a voluntary system for reporting adverse events, MvPI plays a pivotal role in protecting patient health and preventing the recurrence of device-related issues. Its systematic approach to identifying, analyzing, and addressing medical device concerns not only enhances safety and efficiency but also drives continuous improvements in device design. This dedication to safeguarding public health builds trust and confidence among patients, healthcare providers, and stakeholders. Thank you to the entire MvPI team for your unwavering commitment to prioritizing patient safety and advancing healthcare standards.

Medical Device Monitoring Centers (MDMCs) in MvPI

Under the Materiovigilance Programme of India (MvPI), 501 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

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