

# e-Newsletter

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## 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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## New MDMCs

#### Medical Device Adverse Event Monitoring Centres (MDMCs)

01 D Pa

Amandeep Hospital Dalhousie Road, Mamoon, Pathankot, Punjab - 145001 Type of Hospital: Non-Government

Coordinator: Mr.Rajesh

**Deputy Coordinator: Mr. Vishal** 

E-mail ID: ahtk.biomedical@amandeephospital.org

Type of Hospital: Non-Government

Coordinator: Mr. Darshan

Deputy Coordinator: Mr. Ravish

E-mail ID: ah.bme@amandeephospital.org

Amandeep Hospital Model Town, G.T. Road, Amritsar, Punjab - 143001

02

03

Amandeep Medicity
361 Mall Road,
Near Novelty Chowk,
Amritsar, Punjab - 143001

Type of Hospital: Non-Government

Coordinator: Ms. Parveen

**Deputy Coordinator : Mr. Raman** 

E-mail ID: biomedical@amandeepmedicity.org

Type of Hospital: Non-Government
Coordinator: Mr. Ajay Verma
Deputy Coordinator: Mr. Abhishek
E-mail ID: purchase@mmumullana.org

Maharishi Markendeshwar Institute of Medical Sciences & Research Mullana, Ambala, Haryana - 133207

04

05

Amritdhara Hospital (P) Ltd. Karnal, Haryana Type of Hospital: Non-Government Coordinator: Mr. Dharmveer Yadav

Deputy Coordinator: Mr. Dhirendra Kumar E-mail ID: bme.amritdhra@gmail.com

Type of Hospital: Non-Government
Coordinator: Mr. Ramesh Kumar Pandita
Deputy Coordinator: Dr. Neha Dewan

E-mail ID: rameshkumarpandita@qrgmedicare.com

QRG Medicare Hospital Plot No. 1, Sector-16 Faridabad, Haryana - 121002

06

07

Paras Hospital C-1, Shushant Lok, Sector - 43, Gurugram, Haryana - 122002

Type of Hospital: Non-Government

Coordinator: Mr. Paritosh

Deputy Coordinator: Mr. Shatrughan Singh E-mail ID: paritosh.nirbhaya@parashospital.com

Type of Hospital: Non-Government Coordinator: Mr. Abhishek Sharma

**Deputy Coordinator: Mr. Naveen Kumar Pal** 

E-mail ID: abhishek.sharma@fortishealthcare.com

Fortis Hospital Limited Neelam Bata Chowk, NTI, Faridabad, Haryana - 121001

08

09

Government Medical College Dialgam, Anantnag, Jammu & Kashmir - 192210 Type of Hospital: Government
Coordinator: Dr. Sami Manzoor
Deputy Coordinator: Dr. Nasreen Jan
E-mail ID: samimagray070@gmail.com

Type of Hospital: Government Coordinator: Dr. Vishal Tandon

Deputy Coordinator: Dr. Nusrat K. Bhat E-mail ID: dr\_vishal Tandon@yahoo.com

Government Medical College Maheshpura Chowk, Bakshi Nagar, Jammu, Jammu & Kashmir - 180001

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Ramkrishna Care Hospitals
Aurobindo Enclave,
Pachpedi Naka
Dhamtari Road,
Raipur, Chhatisgarh - 492001

Type of Hospital: Non-Government Coordinator: Mr. Jafar Shabaj

**Deputy Coordinator: Mr. Krishna Ramnath Prajapati** 

E-mail ID: jafar.shabaj@carehospital.com

Type of Hospital: Non-Government
Coordinator: Mr. D. Satheesh Kumar
Deputy Coordinator: Mr. PS. Ashik
E-mail ID: ssh.biomedical3@gmail.com

Sai Sanjeevini Hospital Narsimha Puri Colony, Huda Colony, Hyderabad, Telangana

12

13

Prayag Hospital & Research Centre (P) Ltd. Sector - 41, Noida, Gautam Buddh Nagar, Uttar Pradesh - 201301

Type of Hospital: Non-Government Coordinator: Mr. Shubham Goel

**Deputy Coordinator: Mr. Md. Iftekhar Ansari** 

E-mail ID: bme@prayaghospital.in

#### New MDMCs

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Neo Hospital D-170, Sector-50, Noida, Uttar Pradesh - 201301 Type of Hospital: Non-Government

Coordinator: Mr. Krishan

**Deputy Coordinator: Ms. Vaishali** 

E-mail ID: biomedical@neohospital.com

Type of Hospital: Non-Government Coordinator: Mr. Pradeep Kumar Gupta Deputy Coordinator: Mr. Samim Akhatar

E-mail ID: mshivalik@gmail.com

Shivalik Medical Centre
Private Limited
Hoshiyarpur, Sector-51
Noida,Uttar Pradesh - 201301

15

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Sri Aurobindo Medical College & P.G. Institute Indore Ujjanin State Highway, Near MR 10 Road, Madhya Pradesh - 453555

Type of Hospital: Non-Government
Coordinator: Dr. Pooja S. Reddy
Deputy Coordinator: Dr. Anuja Jha
E-mail ID: drpoojasreddy@gmail.com

Type of Hospital: Government Coordinator: Dr. Renuka Munshi

**Deputy Coordinator: Dr. Miteshkumar Maurya** 

E-mail ID: renuka.munshi@gmail.com

Topiwala National
Medical College & BYL Nair
Charitable Hospital
Dr. A.L. Nair Rd.,
Mumbai Central, Mumbai,
Maharashtra-400008

17

18

Vijaynagar Institute of Medical Sciences
Ballari, Karnataka - 583104

Type of Hospital: Government Coordinator: Dr. Y. Vishwanath Deputy Coordinator: Mr. S. Reddy

E-mail ID: vishwanathpharmcology@yahoo.com

Type of Hospital: Non-Government
Coordinator: Dr. Nandita Shenoy
Deputy Coordinator: Mr. Ashok K M
E-mail ID: nandita.shenoy@manipal.edu

Manipal College of Dental Science Light House Hill Road, Mangalore, Karnataka - 575001

19

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Annai Arul Hospital No. 270, Mudichur Road Old Perungalathur Chennai, Tamil Nadu - 600063

Type of Hospital: Non-Government

**Coordinator: Mrs. Sheeba** 

Deputy Coordinator: Mr. S. Sabarigireesan. B E-mail ID: nabh@annaiarulhospital.com 21

BAPS Pramukh Swami Hospital Shri Pramukh Swami Maharaj Marj, Adajan Char Rasta, Adajan, Surat, Gujarat - 395009

Type of Hospital: Non-Government
Coordinator: Mr. Maulik Mangukiya
Deputy Coordinator: Mrs. Mansi Pithwa
E-mail ID: qualitysurat@bapshospital.org

**Type of Hospital: Government** 

**Coordinator:** Dr. Sunil Kumar Mathur **Deputy Coordinator:** Dr. Vandana Goyal

E-mail ID: sunrinty@gmail.com

Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer, Rajasthan - 305001

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Max Super Speciality Hospital
East Block 2,
Press Enclave Road,
Saket, New Delhi - 110017

Type of Hospital: Non-Government Coordinator: Mr. Sourabh Bhardwaj Deputy Coordinator: Mrs. Sita Kapoor

E-mail ID: sourabh.bhardwaj2@maxhealthcare.com

Type of Hospital: Government

**Coordinator:** Dr. Vineet Thomas Abramham **Deputy Coordinator:** Dr. Arup Kumar Mishra

E-mail ID: abramhamvineet@aiimsmangalagiri.edu.in

All India Institute of
Medical Sciences
Mangalagiri, District-Guntur,
Andhra Pradesh - 522503

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Shree Lakshmi Narayana
Institute of Medical Sciences
Osudu, Agaram Village,
Villianur Commune
Kudapakkam,
Puducherry - 605502

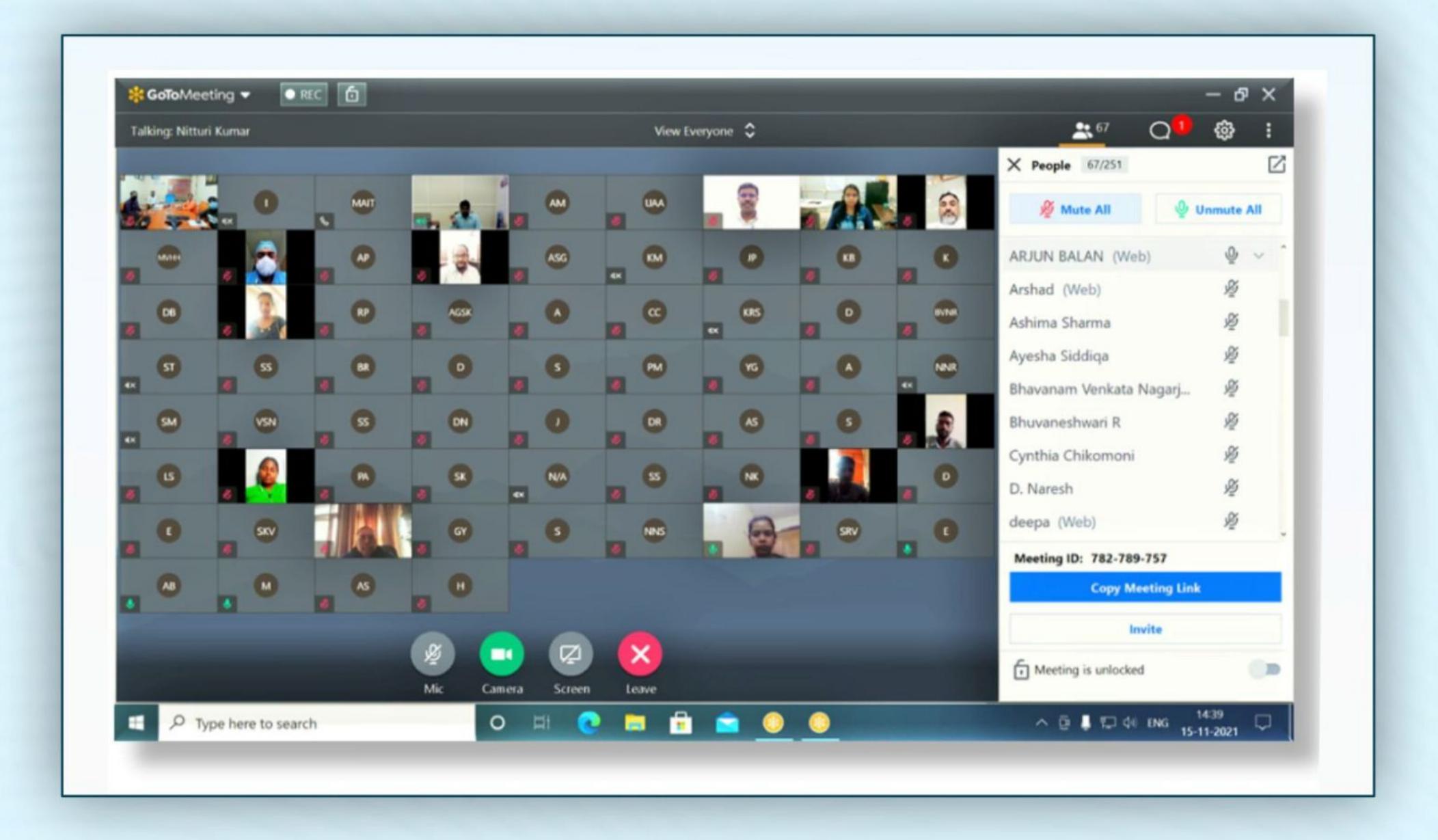
Type of Hospital: Non-Government Coordinator: Dr. S. Nithianandam

Deputy Coordinator: Mr. Mannatheeswaran E-mail ID: nithianandam53@yahoo.co.in

Type of Hospital: Government Coordinator: Dr. Abhishek Ghosh

Deputy Coordinator: Dr. Kushal Banerjee E-mail ID: pharmacology.comjnmh@gmail.com College of Medicine & JNM Hospital Block A2, Road, Kalyani, Nadia, West Bengal

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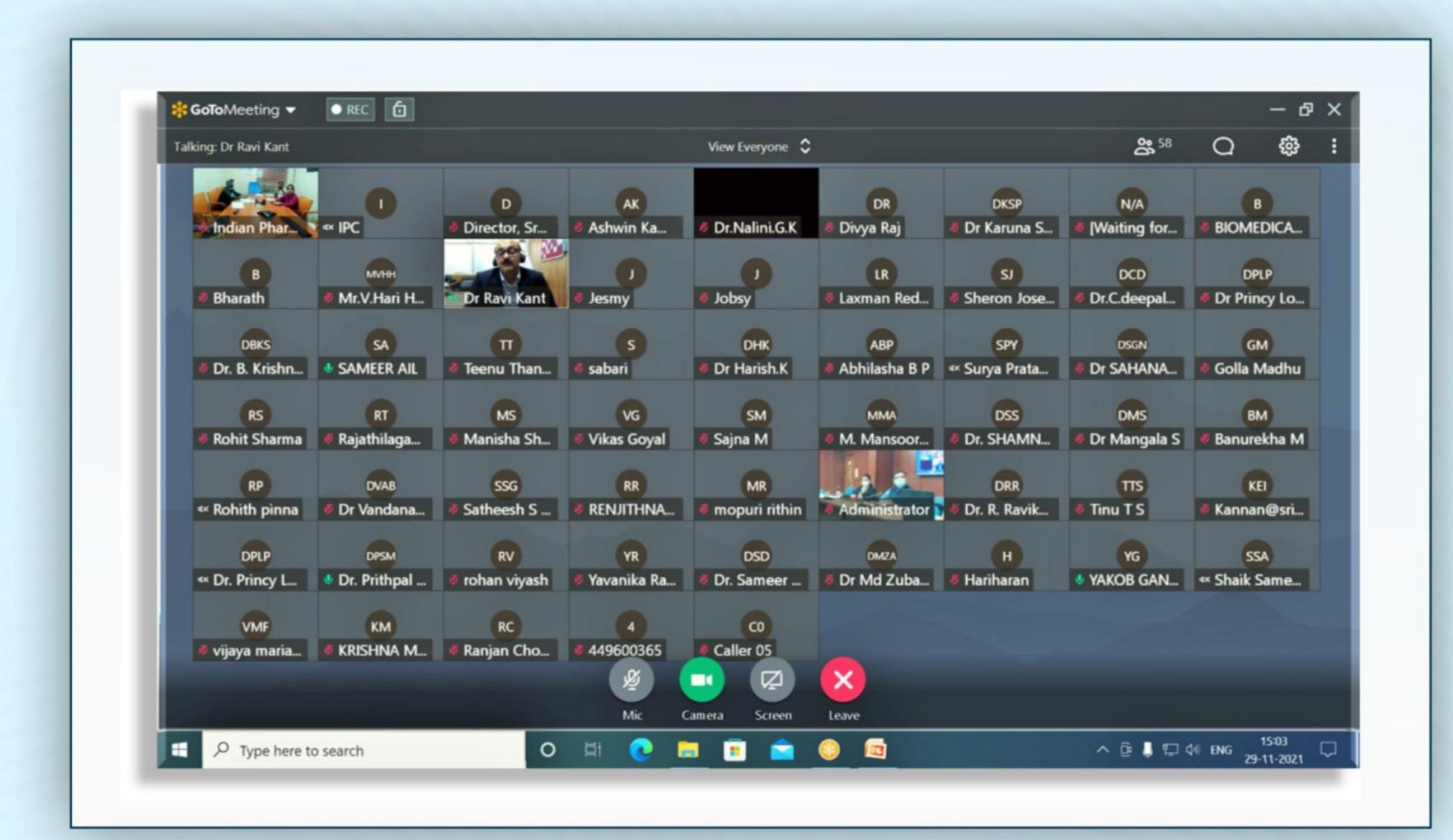


National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI) in association with Andhra Pradesh MedTech Zone, Vishakhapatnam organized a training programme entitled "Role of Biomedical Engineers in assessment of Medical Device Adverse Events" from November 15 to 18, 2021 via digital/virtual platform. This training programme was consists of four sections including two hours per day sessions. In total, 100 participants including biomedical, clinical and service engineers participated in this training programme and enhanced their knowledge on materiovigilance programme, causality assessment and medical device adverse event reporting.

## HIGHLIGHTS

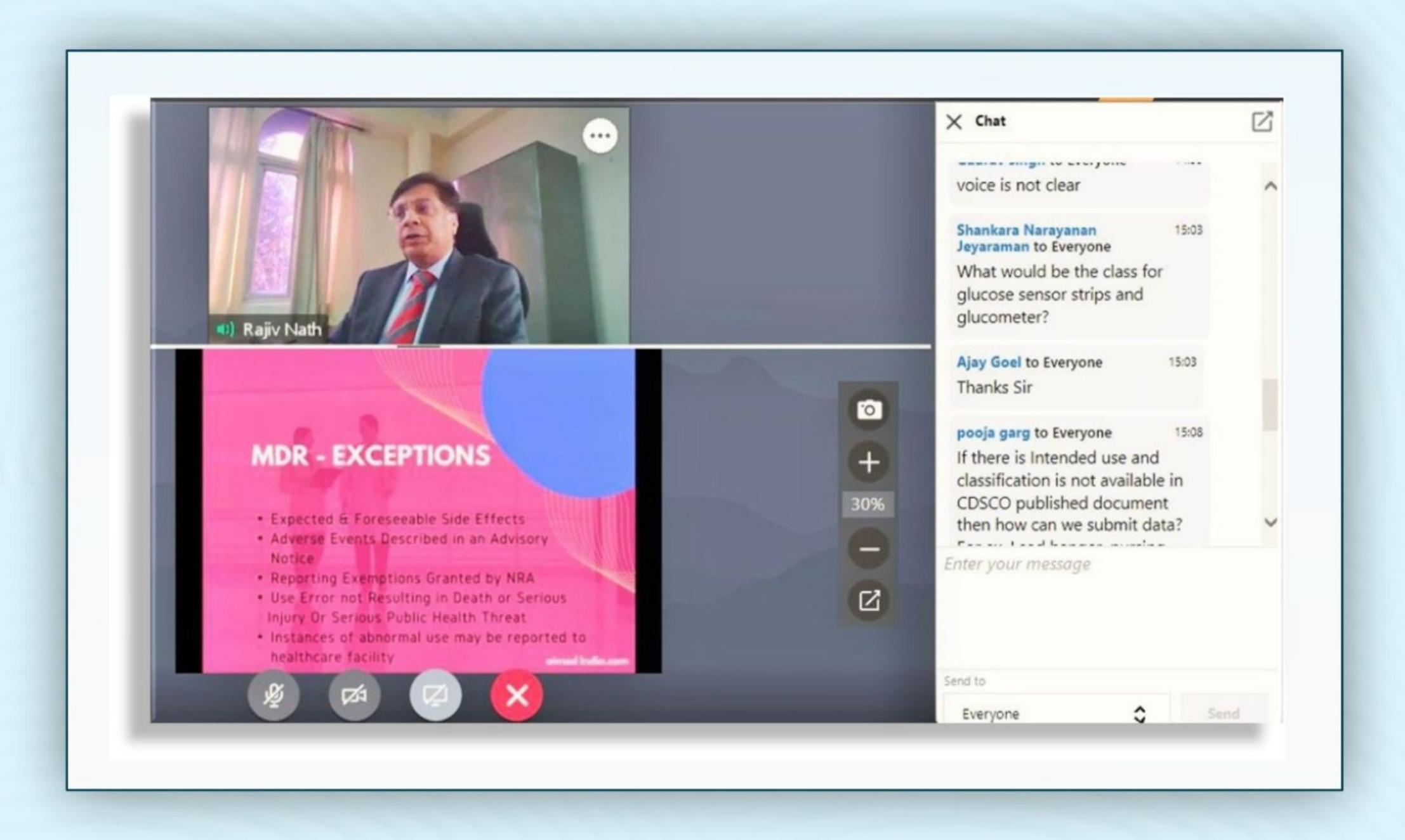
- Participants were encouraged to report medical device adverse event to NCC-MvPI.
- Participants were also advised to strengthen the materiovigilance programme at their respective region.
- Biomedical engineers were highly interested in materiovigilance programme and also shown their interest in materiovigilance projectbased study.





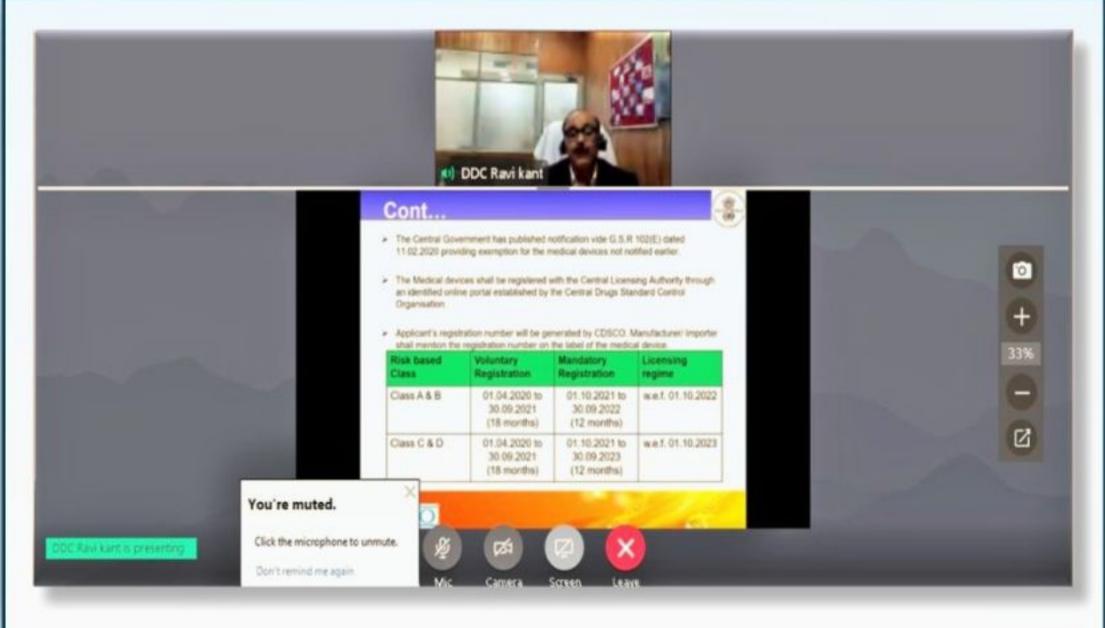
National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI) digitally organized an Induction-cum-training programme for coordinators/deputy coordinators/ materiovigilance associates of newly identified MDMCs from November 29-30, 2021. NCC-MvPI, IPC has recognized 23 new Medical Device Adverse Event Monitoring Centres (MDMCs) pan India during the month of July, August and September. For the seamless functioning of materiovigilance programme at the centres, NCC-MvPI organized this training programme. The training programme organized to develop the basic understanding of newly identified coordinators, deputy coordinators, materiovigilance associates on medical device rules, materiovigilance programme, available tools for reporting, post-marketing surveillance, baseline Study of medical devices. Approx. 60 participants participated in this training programme. Eminent speakers from Central Drugs Standard Control Organization (CDSCO), New Delhi, Sree Chitra Tirunal Institute of Medical Sciences (SCTIMST), Trivandrum, National Health System Resource Centre (NHSRC), New Delhi, JSS Medical College, Mysuru, Abbott India Private Limited and Boston Scientific India Private Limited enlightened the audience with their knowledge and vast experience.

#### TRAINING & EDUCATION

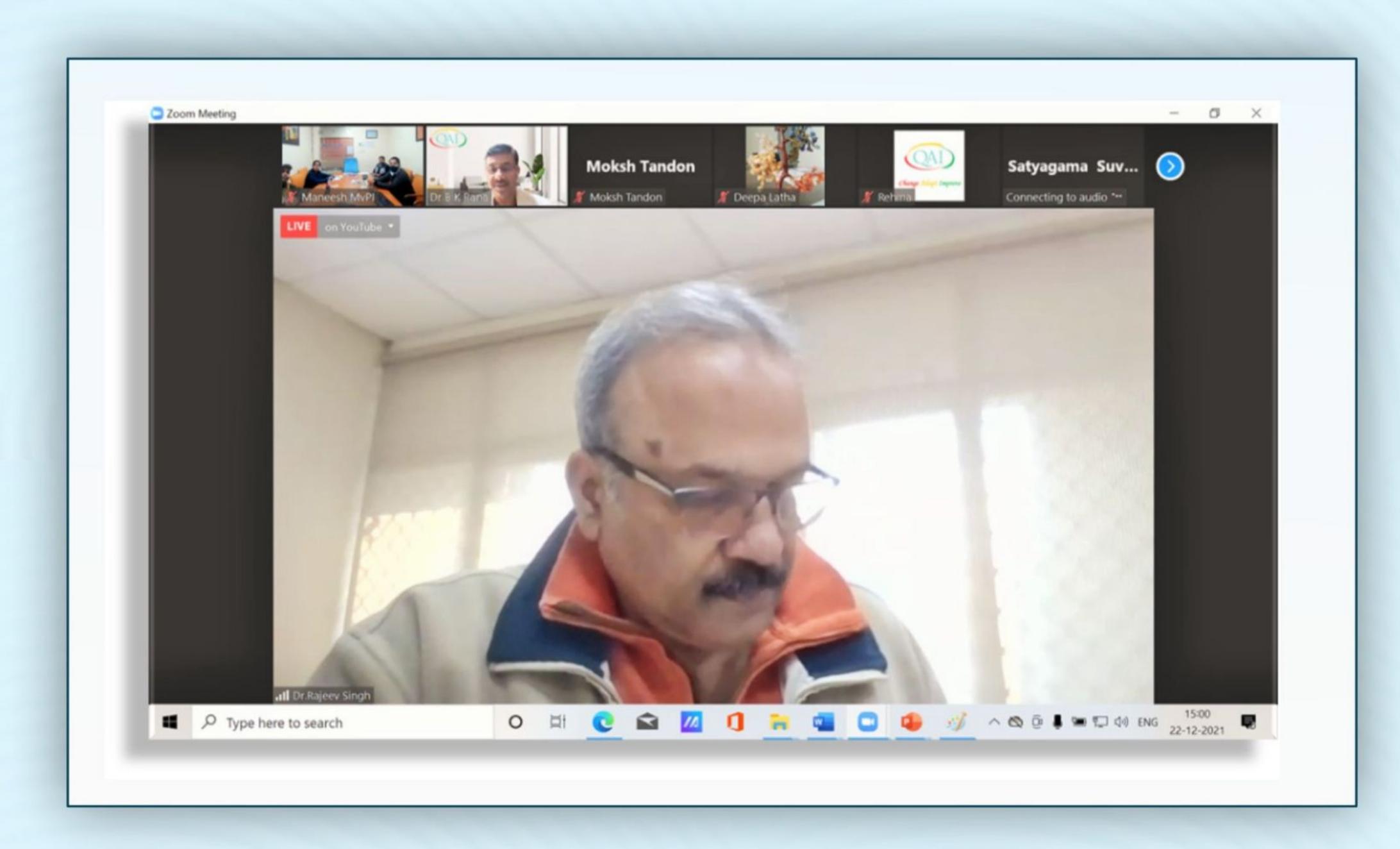


National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI) organized a webinar on "Key role of medical technology/ medical device industries in Materiovigilance programme of India" in association with CDSCO and Association of Indian Medical Device Industry (AIMED) on December 10, 2021.

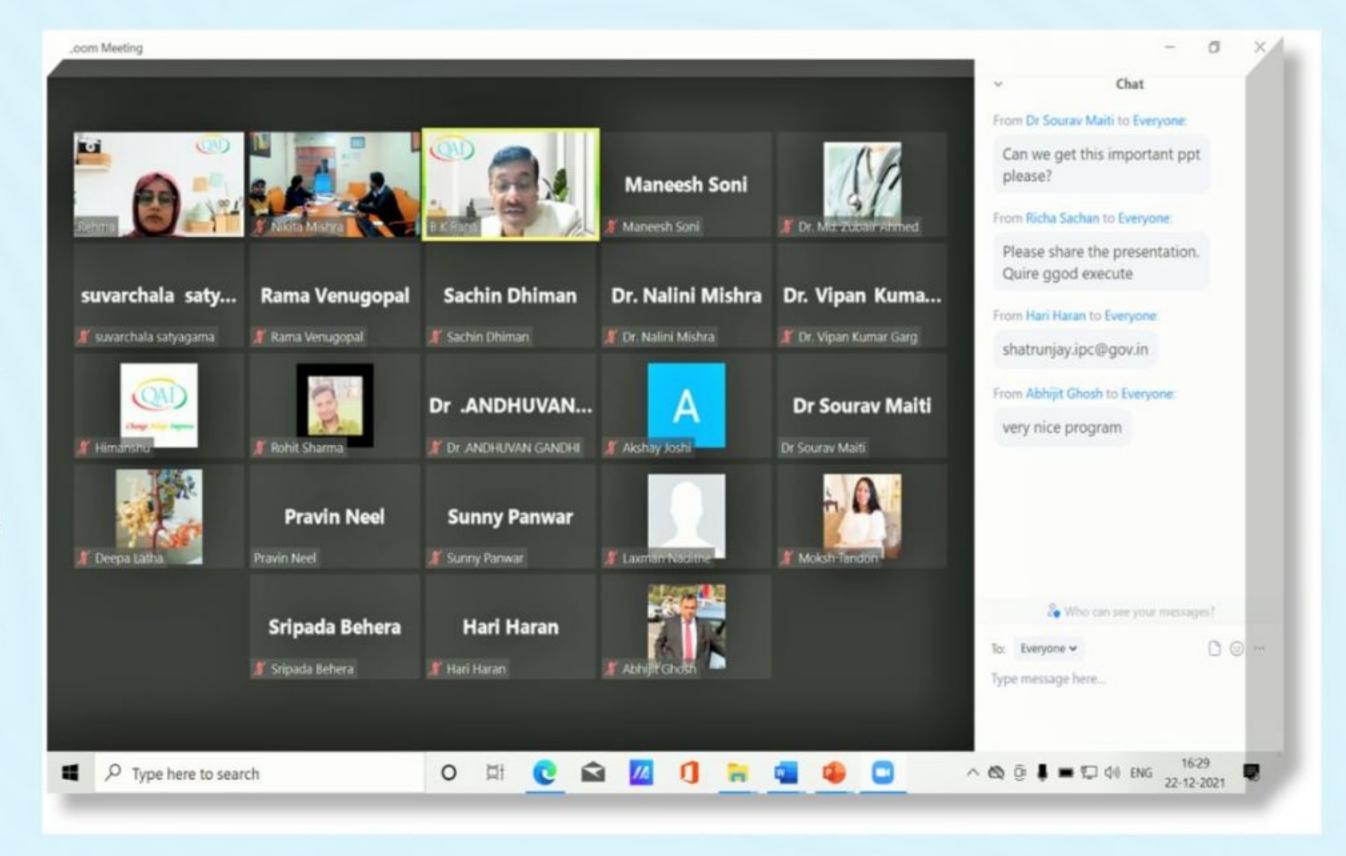




Dr. Ravi Kant Sharma, Deputy Drugs importance of medical device adverse event Controller, CDSCO, Dr. Jitendra Sharma, reporting in India. In total, 60 participants Managing Director & Chief Executive Officer, participated in this webinar and enhanced Andhra Pradesh MedTech Zone (AMTZ) and their knowledge on Medical Device Rules, Mr. Rajiv Nath, Forum Coordinator, AIMED 2017 and reporting of medical device grabbed the attention of the audience on the adverse events.



National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI) in association with Quality & Accreditation Institute (QAI) organized a webinar on "Brain Storming session on integration of medical devices testing centres/labs in Materiovigilance Programme" on December 22, 2021



Representative from different medical device industries participated in this webinar. In the webinar, Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific, Director, IPC presented the special remarks followed by the opening remarks of Dr. B K Rana, Chief Executive Officer, QAI. In total, 35 participants participated in this webinar and developed their basic understanding on materiovigilance programme and adverse event reporting associated with the medical devices.





National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI) physically conducted a training programme at Prayag Hospital, Noida on "Overview of materiovigilance programme and reporting of medical device adverse events" on February 22, 2022 for healthcare professionals including doctors, nurses, technicians and biomedical engineers.

Ms. Nikita Mishra and Mr. Rohit Sharma from MvPI sensitized 40 healthcare professionals including doctors, technicians, biomedical engineers, nurses, pharmacists and dieticians of prayag hospital on programme objectives and medical device adverse events reporting.

MvPI team also interacted with the audience and resolved their query and concern related to materiovigilance programme. MvPI team detailed the audience about knowledge, attitude and practice-based questionnaire for healthcare professionals and also encouraged them to participate in MvPI research study.



National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI) organized an Induction-cum-training programme for coordinators/ deputy coordinators/ materiovigilance associates of newly identified MDMCs from February 24-25, 2022 via digital/virtual platform. NCC-MvPI, IPC has recognized 26 new Medical Device Adverse Event Monitoring Centres (MDMC) pan India during the month of October, November and December. For the seamless functioning of materiovigilance programme at the centres, NCC-MvPI organized this training programme. The training programme organized to cultivate the elementary understanding of newly identified coordinators, deputy coordinators, materiovigilance associates on medical device rules, materiovigilance programme, available tools for reporting, post-marketing surveillance and baseline study of medical devices. In total, 100 participants participated in this training programme. Pharmacy students from National Institute of Pharmaceutical Education and Research (NIPER), Hyderabad and AL Ameen College of Pharmacy, Karnataka also participated in this training programme.



### TRAINING & EDUCATION

National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI) physically conducted a training programme at QRG Medical Hospital, Faridabad on "Overview of Materiovigilance programme and reporting of medical device adverse events" on February 28, 2022 for healthcare professionals including doctors, nurses, technicians and biomedical engineers.



Ms. Nikita Mishra and Mr. Rohit Sharma sensitized 25 healthcare professionals including doctors, technicians, biomedical engineers, nurses and pharmacists of QRG Medical Hospital on Materiovigilance programme and reporting of medical device adverse events. MvPI team also solved the cross-questions done by the audience related to materiovigilance programme. MvPI team detailed the audience about knowledge, attitude and practice-based questionnaire for healthcare professionals and also encouraged them to participate in MvPI research study.

## Medical Device Adverse Event Monitoring Centres (MDMCs)

All India Institute of Medical Sciences, Bhopal physically conducted a training programme on "Significance of Materiovigilance programme in India" for the nursing students on January 24, 2022. In total, 70 participants participated in this training programme and build their knowledge on basics of Materiovigilance programme, causality assessment and hands on training on medical device adverse event reporting. Dr. Shilpa N Kaore, coordinator, AIIMS Bhopal trained the audience with her knowledge and vast experience.



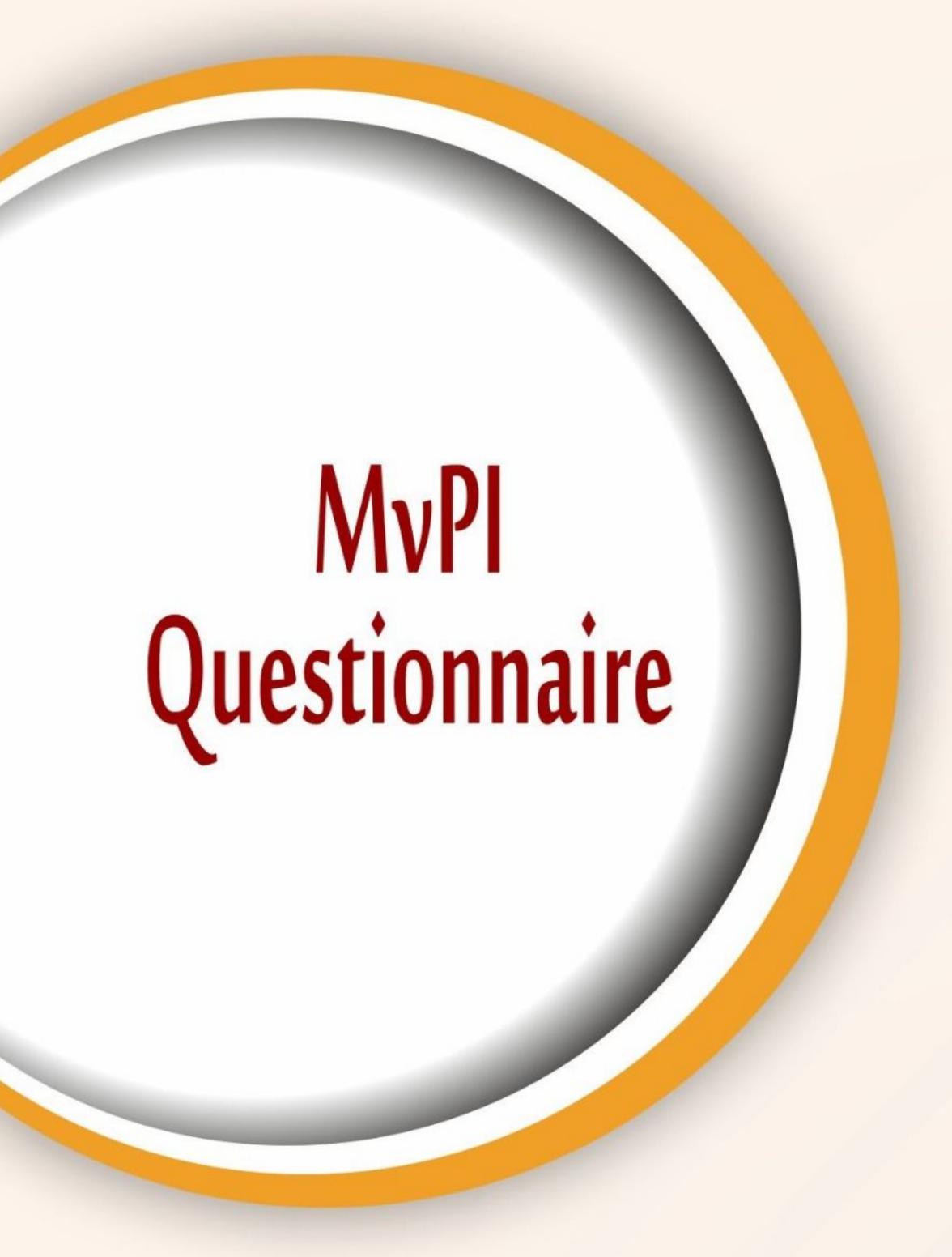
## Visit of MvPI Team at medical device adverse event monitoring centres

To strengthen the materiovigilance programme at medical device adverse event monitoring centres, Mr. Manish Soni, Ms. Nikita Mishra and Mr. Rohit Sharma from MvPI visited the following centres of Noida and Faridabad region on February 22 & February 28, 2022.

- Shivalik Medical Centre Private Limited, Noida, Uttar Pradesh
- · Neo Hospital, Noida, Uttar Pradesh
- Prayag Hospital & Research Centre Private Limited, Noida, Uttar Pradesh



Glimpse of MvP1 team visit at the monitoring centres



NCC-MvP1, IPC has designed "Knowledge, Attitude & Practice-based Questionnaire" study to assess the present readiness of all health care professionals including doctors, nurses, pharmacists, biomedical engineers, and persons actively involved in uses, testing, storage and purchase of medical devices including invitro diagnostics on "Safety surveillance practice of medical devices in India".

#### Note

All the healthcare professionals are requested to participate in the MvPI research study and make a meaningful contribution at a national cause.

#### **Questionnaire Link:**

https://docs.google.com/forms/d/e/1FAIpQLScdFcz8Mh9JUCziP820klizeghXhzmH4USkO4bHpRXNU\_0JDw/viewform?usp=sf\_link

Knowledge, Attitude & Practice of Healthcare Professionals on Safety	*	•	
Surveillance of Medical Devices in India			
This questionnaire is a part of research study. The information will be kept strictly confidential and entirely be used for research purpose only.			
Email *			
Valid email			
This form is collecting emails. Change settings			

## COORDINATOR'S FEEDBACK



Dr. Sana Rehman

Deputy Coordinator, AMC & MDMC at HIMSR Assistant Professor, Dept. of Pharmacology HIMSR, Jamia Hamdard New Delhi - 110062

Congratulations to NCC-MvPI, IPC for being the WHO collaborating Centre for Pharmacovigilance in Public Health Programmes & Regulatory Services. MvPl is a great initiative. Medical devices, being life-saving tools, are considered to be a boon for healthcare system. Although medical devices benefit the patients by facilitating the diagnosis and management, its use is not entirely risk-free. Identification and reporting of any adverse event that resulted from the usage of the medical equipment is important for patient safety which is the primary responsibility of all healthcare professionals. In recent years, we have come across an increased incidence of adverse events following medical device usage. With the initiative of MvPI, doctors are sensitized to any medical device adverse event and even reporting of these events. HIMSR & associated HAHC hospital was enrolled as a medical device monitoring centre (MDMC) under MvPI in October 2019. Various Materiovigilance activities have been carried out effectively under the supervision of Professor Arunabha Ray, Coordinator, AMC & MDMC at HIMSR along with the effortless support of Ms Sabitri Pandit. This centre has constituted a Materiovigilance committee who work enthusiastically in sensitizing healthcare professionals for MDAE reporting regularly. Any adverse event following the usage of medical equipment are collected from different departments and collated. It has been a great pleasure working with MvPI and I along with my team shall continue to contribute the same in future for the betterment of public health.



# Publication

ational Coordination Centre - Materiovigilance Programme of India (NCC-MvPI) published an article entitled "Acute intraocular toxicity caused by perfluorocarbon liquids: safety control systems of medical devices" in Graefe's Archive for Clinical and Experimental Ophthalmology.

(DOI: https://doi.org/10.1007/s00417-022-05578-w).



Review Article Published: 05 February 2022

Acute intraocular toxicity caused by perfluorocarbon liquids: safety control systems of medical devices

<u>Girish K. Srivastava</u> ✓, <u>Vivekanandan Kalaiselvan</u>, <u>Cristina Andrés-Iglesias</u>, <u>Shatrunajay</u> <u>Shukla</u>, <u>Rohit Saxena</u> & <u>Jose Carlos Pastor</u>

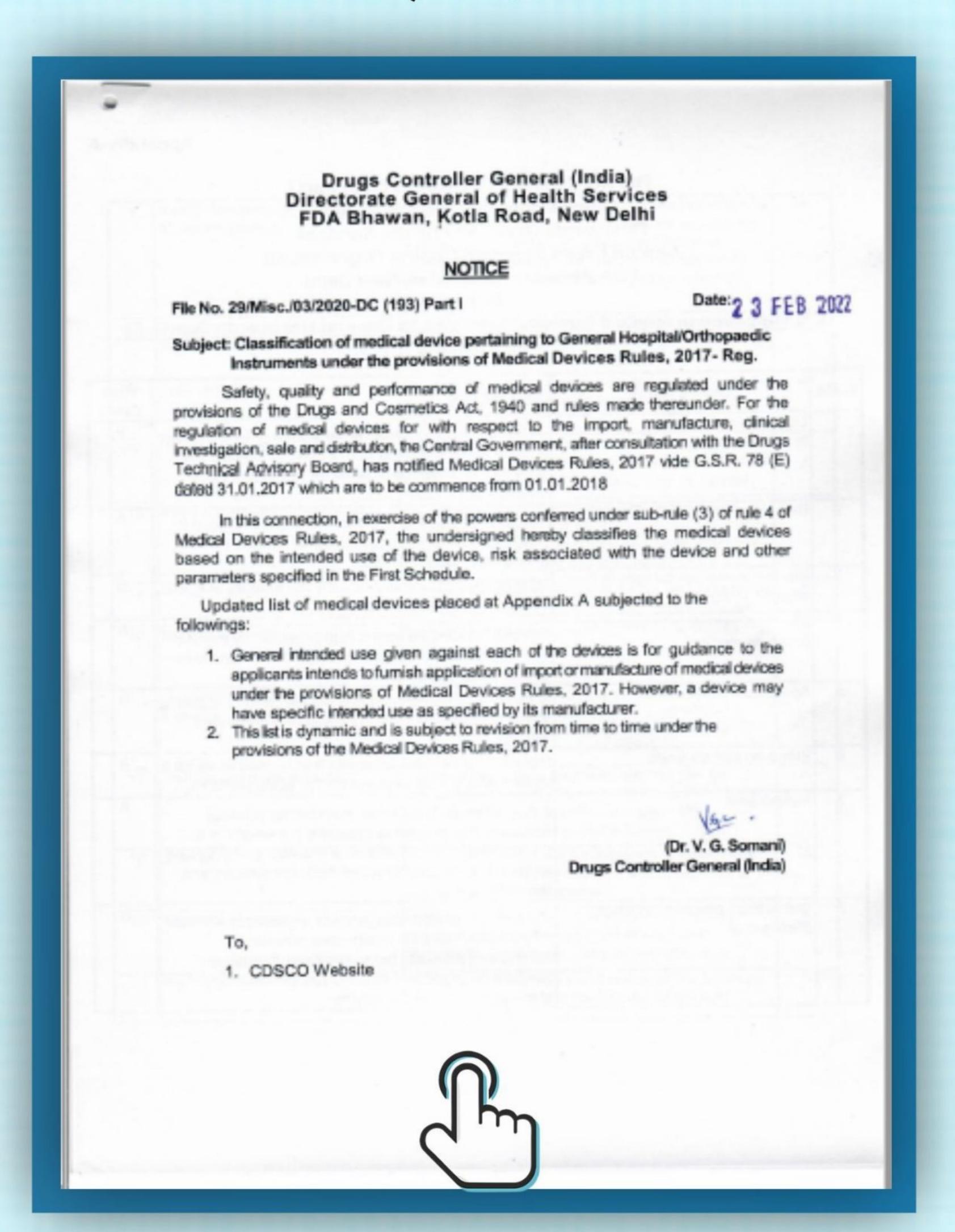
Graefe's Archive for Clinical and Experimental Ophthalmology (2022) Cite this article

MATERIOVIGILANCE PROGRAMME OF INDIA (MVPI)

# MEDICAL DEVICE UPDATE



Central Drugs Standard Control Organization (CDSCO) classified the medical devices pertaining to General Hospital/Orthopaedic instruments under the provisions of Medical Device Rules, 2017.





## SAFETY ALERTS

NCC-MvPI, IPC has observed an adverse event report of Infection followed by vision loss after Implantation associated with AcryS of Single piece IOL which may lead to serious adverse event.

S. No.	Suspected Device Details		Event Details
	Device Name	Manufacturer	
1	AcrySof Single piece IOL	Alcon Laboratories, Inc	Infection followed by vision loss after Implantation

NCC-MvPI, IPC has observed certain adverse event reports of short circuit associated with Syringe pump which may lead to serious adverse event.

S. No.	Suspected Device Details		Event Details
	Device Name	Manufacturer	
1	Syringe pump	Alliance Medicaid	Short Circuit



## SAFETY ALERTS

NCC-MvPI, IPC has observed certain adverse event reports of Implant break/Implant bent after implantation associated with Internal orthopedic fixation which may lead to serious adverse event.

S. No.	Suspected Device Details		Event Details
	Device Name	Manufacturer	
1	Internal orthopedic fixation system	M/s Changzhou, Kanghui Medical Innovation Limited. Imported by India Medtronic Private Limited, Trauson(China) Medical Instrument Limited & Stryker India Private Limited.	Implant break/Implant bent after implantation

NCC-MvPI, IPC has observed an adverse event report of Poor quality and suture frequently get cut off during use associated with MERIL-BONEWAX Suture which may lead to serious adverse event.

S. No.	Suspected Device Details		Event Details
	Device Name	Manufacturer	
1	MERIL-BONEWAX (Model No. BW810)	Meril Endo Surgery Pvt. Ltd.	Poor quality and suture frequently get cut off during use

**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 in medical device adverse event reporting form after the use of these devices to NCC-MvPI, IPC via e-mail: <a href="mailto:shatrunjay.ipc@gov.in">shatrunjay.ipc@gov.in</a>.



www.ipc.gov.in



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NCC-PvPI IPC



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shatrunjay.ipc@gov.in, mvpi-ipc@gov.in



**ADR Mobile-app** 



## Indian Pharmacopoeia Commission Ministry of Health & Family Welfare Government of India

Sector-23, Raj Nagar, Ghaziabad - 201002 Tel.: 0120-2783400, 2783401, 2783392 Fax: 0120-2783311 For any other Information/Suggestion Query Contact:

Materiovigilance Programme of India
Email: lab.ipc@gov.in, mvpi.ipcindia@gmail.com
Website: www.ipc.gov.in

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