ROYAL CARE HOSPITALS
making life better

NABH ACCREDITED
H-2022-0901

STEPPING FORWARD TO PROMOTE SAFETY OF MEDICAL DEVICES : **MATERIOVIGILANCE PROGRAM OF INDIA**

Patron
Dr. K. Madeswaran M.Ch.,
Chairman and Managing Director
Consultant Neuro & Spine Surgeon
Royal Care Super Speciality Hospital

16th Feb 2024 Friday
Venue: Hotel Gokulam Park, Coimbatore.

Organized By
Medical Device Adverse Event Monitoring Centre &
Department of Biomedical Engineering
Royal Care Super Speciality Hospital, Coimbatore.
Jointly With
National Coordination Centre-Materiovigilance Programme of India
Indian Pharmacopoeia Commission, Ghaziabad.
an Autonomous Institution of MoH&FW, Govt. of India.

OBJECTIVE

To sensitize all the healthcare professionals, manufacturers, importers, distributors and bio-medical engineer students and other stack holders for better understanding of medical device regulatory frameworks, standards and medical device safety through post marketing survillance and also for promoting patient safety through implementing and developing Materiovigilance Program of India (MvPI) in southern region.

BACKGROUND

The Ministry of Health and Family Welfare (MoHFW), Government of India has approved the Materiovigilance Programme in an effort to address potential adverse events related to medical devices in the wake of multiple horrifying occurrences involving faulty medical devices. The Materiovigilance program is to reduce the likelihood re-occurrences of adverse events related to medical devices.

Materiovigilance Programme of India was launched by DCG (I) on 6th July 2015 at Indian Pharmacopoeia Commission, Ghaziabad to monitor the safety of medical devices. This program will help us to

- ☑ Generating India specific adverse event due to medical device
- ☑ Helps in making regulatory decision
- ☑ Assuring the safety of medical devices.

For this Programme Indian Pharmacopoeia Commission (IPC) functions as National Coordination Centre (NCC). Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), Trivandrum act as National Collaboration Centre, National Health System Resource Centre (NHSRC), New Delhi, act as Technical support partner and Central Drugs Standards Control Organization (CDSCO), New Delhi, support MvPI with experience of functioning as National regulator.

THIS WORKSHOP AIMS TO PROVIDE KNOWLEDGE ON:

- ☑ Indian Regulatory Frameworks
- ☑ Medical Device Quality Standard ISO 13485
- ☑ Recent updates on Medical textiles standards
- ☑ National medical device vigilance program: MvPI
- ☑ Hands on training for reporting Adverse Events

WHO IS ELIGIBLE TO PARTICIPATE?

- ☑ All the healthcare professionals from organization and institution
- ☑ Regulatory affairs Executive in Health industries
- ☑ Bio-medical engineers & students
- ☑ Ophthalmologist

EXPECTED OUTCOME

- ☑ To strengthen the MvPI programme in the southern region among MAH in order to take the programme to the next advanced level.
- ☑ Better understating and involvement in Materiovigilance Program form all medical device stakeholders and institutes for time to time updates.
- ☑ Encouraging the students to participate in MvPI internship program.
- ☑ To learn about medical device adverse events, safety updates and reporting tool.

PROGRAMME SCHEDULE

08.30 AM – 09.00 AM	Registration
09.00 AM – 09.15 AM	Pre assessment questionnaires
09.15 AM – 10.00 AM	Programme Inauguration Welcome Address Special address
10.00 AM – 10.30 AM	Regulatory requirements for Post Marketing Surveillance: Medical Devices Rule, 2017
10.30 AM – 11.00 AM	Setting Indian Standards High: Paramount importance in need of standardising medical textiles
11.00 AM – 11.15 AM	*TEA BREAK*
11.15 AM – 11.45 AM	Medical Device safety surveillance systems in India -Materiovigilance Programme of India (MvPI)
11.45 AM – 12.15 PM	MvPI reporting tools and need for action on alerts and recall issued by global regulators
12.15 PM – 01.00 PM	Case Study: Group Exercise & ADRMS Software Demo
01:00 PM – 02:00 PM	*LUNCH BREAK*
02.00 PM – 02.30 PM	Ensuring the quality compliances on Medical Devices: ISO 13485
02.30 PM – 03:00 PM	Risk management in medical device supply chain management
03:00 PM – 03:30 PM	Current challenges and their management in ocular devices
03:30 PM – 03:45 PM	*TEA BREAK*
03.45 PM – 04:15 PM	Panel discussion & feedback
04.15 PM – 04.30 PM	Closing remarks

Inaugurated by:

Dr. K. Madeswaran M.Ch.,
Chairman and Managing Director
Royal Care Super Speciality Hospital

Dr. V. Kalaiselvan,
Senior Principal Scientific Officer - MvPI,
Indian Pharmacopoeia Commission (IPC), Ghaziabad.

Felicitation:

Dr. B. Paranthaman Sethupathi
Medical Director

Dr. K.T. Manisenthilkumar
Chief Operating Officer

Welcome address:

Dr. D. Gandhiraj,
MDMC - coordinator, Chief Microbiologist & Head-Quality Systems

Dr.K.M.Srinivasan,
Deputy Drug Controller (India),
CDSCO south zone office, Chennai

Dr. V. Kalaiselvan,
Senior Principal Scientific Officer - MvPI,
Indian Pharmacopoeia Commission (IPC),
Ghaziabad.

Dr. Ranjan Kumar Choudhury
Advisor- Healthcare Technology, National Health Systems Resource Centre (NHSRC), Delhi

Dr. Shatrunjay Sukhla,
Scientific Assistant - MvPI,
Indian Pharmacopoeia Commission(IPC),
Ghaziabad

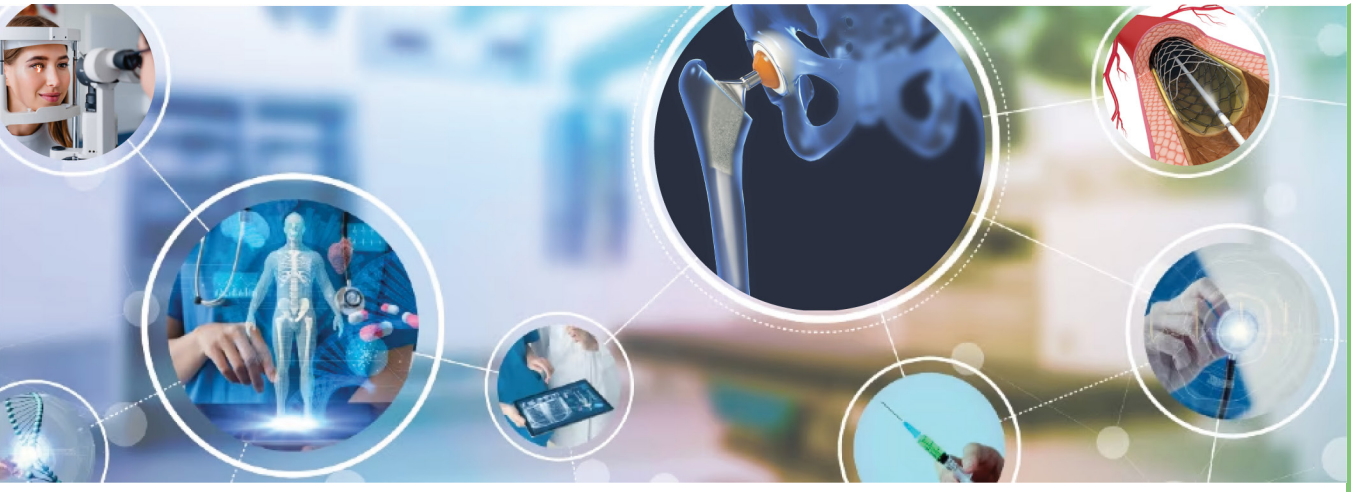
Dr. Senthil Kumar
Medical Superintendent and professor of Ophthalmology, Omandurar government hospital, Chennai

Dr. E. Santhini
Head In-Charge of CoE Medical Textiles,
SITRA LAB, Coimbatore

Mr. Hariharan
Senior Materiovigilance Associate - MvPI,
Reginal Training Center -National Institute of Mental Health and Neuro sciences, (RTC-NIMHANS), Bangalore.

Mrs. Abirami
Materiovigilance Associate – MvPI,
MDMC - Royal Care Super Speciality Hospital,
Coimbatore

ARE YOU EAGER TO LEARN MORE ABOUT THE INDIAN REGULATION, MONITORING AND REPORTING OF MEDICAL DEVICE ADVERSE EVENT?



REGISTRATION DETAILS:

For medical device & textile Industry officials, healthcare organization & other HCP's	₹ 2000
For students	₹ 1000

registration opens From 20th Jan to 12th feb

CLICK HERE TO REGISTER

Royal Care Super Speciality Hospital Limited

No:1/520, Neelambur, Sulur Taluk, Coimbatore - 641 062, Ph: 0422-222 7000, 22 77 000
E-mail: contact@royalcarehospitals.in, Web: www.royalcarehospitals.in