



Patron
Dr. K. Madeswaran, M.Ch.,
Chairman
Royal Care Super Speciality Hospital

Training Programme on
**Management and Ensuring
Safety of Medical Devices**
22nd June 2019 Saturday

Venue : Hotel Gokulam Park, Coimbatore.



Organized By :
Department of Biomedical Engineering
Royal Care Super Speciality Hospital
Jointly With Indian Pharmacopoeia Commission,
Ministry Of Health Govt. of India, Ghaziabad.



OBJECTIVE

To sensitize healthcare professionals, manufacturers, importers & distributors of medical devices including all other healthcare stakeholders for better understanding of management and safety of medical devices and also for promoting patient well-being, strengthening of Materiovigilance system and to aware our stakeholders about the necessity and importance of medical devices adverse events (MDAE) reporting.

patient safety. As the new Medical Device Rules 2017 being effective from January 2018, the MvPI programme of Ministry of Health and Family Welfare, Govt. of India under the aegis of IPC is imperative for the successful Medical Device Adverse Event Reporting in the country.

MvPI aims to promote and facilitate adverse event reporting of Medical Devices and subsequently evaluating these events. The scientific and systematic evaluation of these medical device events/reports will foster monitoring trends for improving and protecting the health and safety of patients. As medical devices industries are one of the major stakeholders of MvPI, their participation needs to be encouraged to make significant impact in the outcome.



BACKGROUND

Indian Pharmacopoeia Commission (IPC), an autonomous institution of Ministry of Health and Family Welfare, Government of India, has been entrusted with National Coordination Centre responsibilities related to Materiovigilance Programme of India (MvPI) since January 2018 with an objective to improving Indian patient safety by monitoring, recording, analyzing root cause of adverse events or risks associated with use of medical devices & suggesting regulatory bodies for appropriate action with a sole intention of improving



Nerve Monitor



ABOUT THE TRAINING

This training aims at addressing the following issues :-

- ▶ To sensitize Healthcare stake holders about Medical Devices Regulation in India.
- ▶ Risk Management during pre and post-market phase
- ▶ To ensure patient safety by educating Healthcare stake holders about Materiovigilance Programme of India (MvPI) and modalities of AE reporting
- ▶ To ensure effective AE reporting culture among MDMCs, clinicians, biomedical engineers, hospital biotechnology staff and other Health care Professionals



EXPECTED OUTCOME

Better understanding of Medical Devices Regulations prevailing in India Knowledge on how to tackle risks associated with Medical Devices during pre and post-market phase Enabling medical device manufacturers, users and other stakeholders by disseminating information on how to report, when to report and what to report and what not to report to IPC, NCC-MvPI Strengthening of effective Materiovigilance system across the country.



O-ARM Navigation



WHO WILL ATTEND ?

- ▶ Healthcare Professionals working in medical device industry.
- ▶ Regulatory affairs executives in health industry.
- ▶ Biomedical engineers / Bio medical Professionals from hospitals/ medical device industry Academicians.



FACULTY

Dr. Kalai Selvan,
NCC-MvPI Principle Scientist, IPC Govt.India,
Ministry of Health and Family Welfare, Delhi

Dr. Ajai Basil,
NHSRC.Govt.India,
Ministry of Health and Family Welfare, Delhi

Mrs. Shanthi Gunasekaran
Deputy Drugs Controller
Control Drugs Standard Central Org. South Zone

Mr. Hariharan,
Research Associate, Narayan Hiruthalaya Hospital, Bengaluru.

Mr. D. Gandhi Raj,
Head Of Quality System Department, Co-Ordinator MvPI,
Royal Care Super Speciality Hospital, Coimbatore.



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