सत्यमेव जयते

IPC

e-Newsletter

VOL 1 | ISSUE 4 | 2019

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

CONTENT

New MDMCs

Saheed Laxman Nayak Medical College
and Hospital Koraput (Orissa)

Maratha Mandals Nathajirao G. Halgekar Institute
of Dental Sciences & Research Centre
Belgaum (Karnataka)

All India Institute of Medical Sciences
Bhopal (Madhya Pradesh)

Konaseema Institute of Medical Sciences &
Research Foundation
Amalapuram (Andhra Pradesh)

Training & Education

Ms. Milu Thomson, MvPI Official sensitized on the functioning of Materiovigilance Programme of India and the concepts of medical device adverse event reporting in One-Day Workshop on Testing and Callibration of Medical Devices at Kalam Convention Centre, AMTZ Campus, Visakhapatnam on 31st July, 2019. Around 100 participants were present this workshop.

Mr. Hari Haran, MvPI Official interacted and created awareness on the reporting tool for medical device adverse event reporting in a Two Day Workshop on Healthcare Information Technology at MGM Healthcare, Chennai on 9th & 10th August, 2019. Around 30 healthcare professionals participated in this workshop.

Dr. Bikash Medhi from PGIMER, Chandigarh one of the MDMC under MvPI conducted an awareness programme on 3rd August 2019 at Maratha Mandals Nathajirao G. Halgekar Institute of Dental Sciences & Research Centre, Belgaum, Karnataka. More than 200 members participated in the awareness programme with more discussions on the scope and current status of MvPI in India.

Training & Education

A session on Materiovigilance Programme of India "concept & terminologies" was given by Dr. Shatrunjay Shukla at SIPRA Labs, Hyderabad. He also visited the lab and enhanced his knowledge on Medical Device Testing including physico-chemical and biological testings of Copper-T, Condoms, Sterile Hypodermic Needles, Tubal Rings, Hypodermic Syrignes & Blood Bags.

Medical Device	Parameter Tested
Copper-T	Shape determination, measurement, tensile force, stability, visco elastic property, in-situ detection, identification of barium and sulphate and clinical evaluation etc.
Condoms	Bursting volume and pressure, dimensions, visible defects, mirobial contamination, force and elongation at break of test pieces of condoms, shelf life based on accelerated
Sterile Hypodermic Needles	Size designation, color coding, needle hub; cap; tube; point, biocompatibility, patency of lumen, tolerance on graudated capacity, penetration force and drag force for needles etc.
Tubal Rings	Fracture test, memory test, fatigue test, test for sterility; extracts, implantation test etc.
Hypodermic Syrignes	Determination of limits for acidity or alkalinity; extractable metals, lubricant, tolerance
Blood Bags	Dimensions, air content, anti coagulant or preservative solution etc.

Sipra Labs, one of the Medical Device Testing Laboratory providing following services :-

- **OECD GLP compliant Biocompatibility testing of medical devices as per ISO 10993**
- **Chemical testing of devices as per ISO standards**
- **NABL ISO 11607 compliant packaging material testing of the medical devices**

Updates on Medical Devices

Constitution of medical devices technical advisory group has been decided to advice CDSCO on matter related to regulation of medical devices.

PURPOSE

- To examine the issues relating to implementation of medical devices regulations
- To suggest CDSCO regarding strenghthening of medical devices regulations in the country including Make in India, ease of doing business and taking-up matters with DCC, DTAB and Ministry as per requirement.

ICMR after deliberations with national consultation has released national essential diagnostics list in line to WHO Essential Diagnostics List (EDL) and Regulatory Provisions of diagnostics, CDSCO for quality assurance and strengthening of laboratory capacity across the health sytem for diagnostic services. This list would provide guidance to the government for deciding the kind of diagnostic tests that different healthcare facilities-sub centre / HWC, primary health centre, community health centre, sub-district hospital, and district hospital require.

BIS publishes IS 23485 Medical Devices – Quality Management System Requirements and Essential Principles of Safety & Performance for Medical Devices

IS 23485 Medical Devices – Quality Management System requirements and Essential Principles of safety & performance for Medical Devices has been formulated by amalgamation of ISO 13485 : 2016, 16142-1 : 2016 & 16142-2:2017.

Implementation of this standard by an organization would encompass compliance to "essential principles of safety and performance as well as to QMS requirements; which include risk evaluation and management for the designing and manufacturing of medical devices, clinical evaluation, bio compatibility verification, environmental effects' assessment, software validation and other safety and performance related aspects likely to be encountered during entire life cycle of a medical device.

Role of Subject Expert in Materiovigilance Programme

Subject Expert Group has been constituted by Indian Pharmacopoeia Commission (IPC), Ghaziabad to review the interpretation drawn from the collated data related to particular devices such as cardiac stents, orthopaedic implant, intra-uterine contraceptive devices

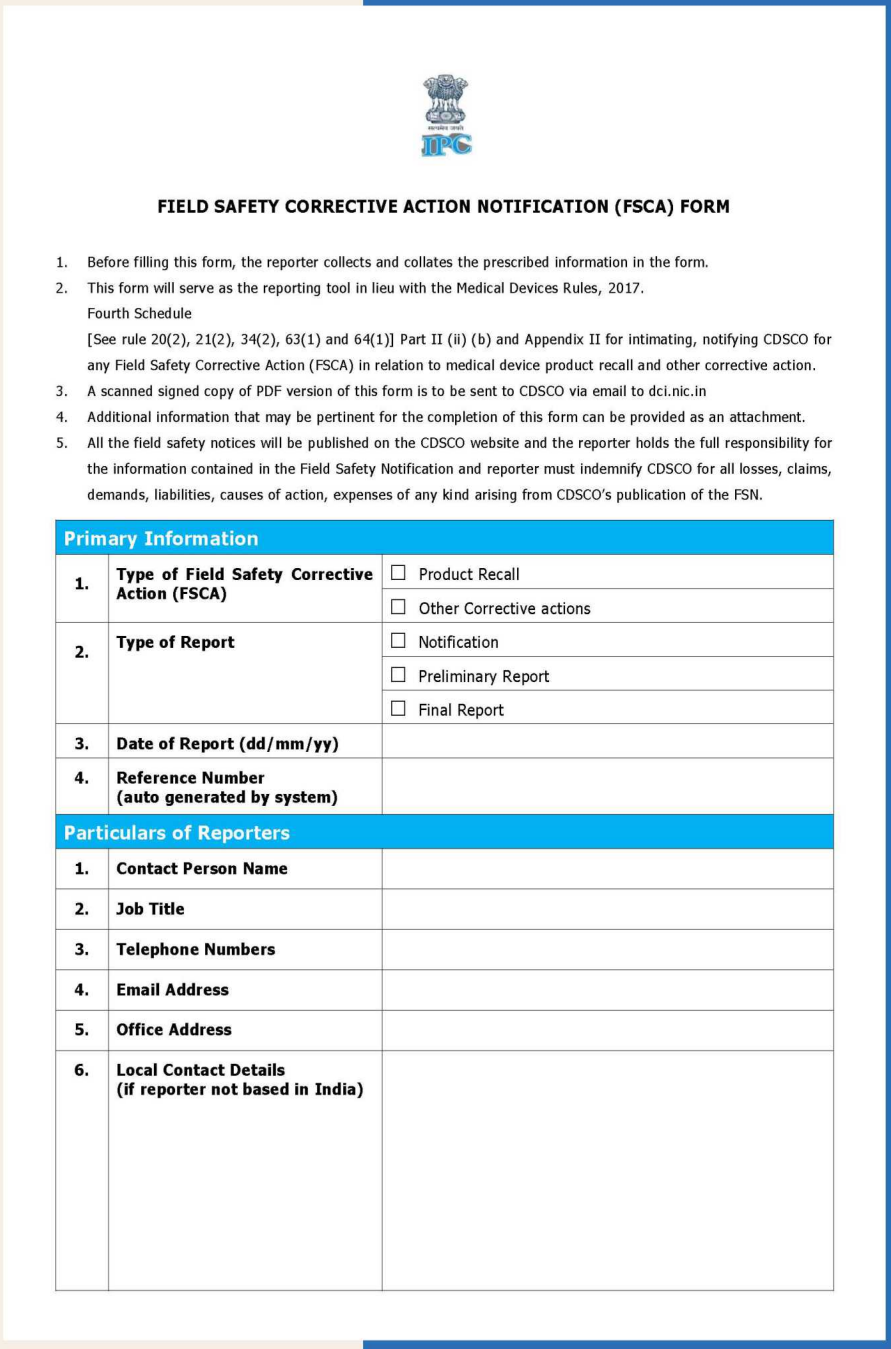
- **To review quality and completeness of data in the Medical Device Adverse Event (MDAE) reporting**
- **To review the causality assessment of MDAEs**
- **To make recommendations to the Core Technical Committee after data analysis and review**
- **To devise formats, guidance documents for follow up actions after implementation of recommendations**

If you are interested in contributing your expertise kindly email us on mvpi.ipcindia@gmail.com

Notify changes through FSCA

As per MDR 2017, the licensee shall inform the State Licensing Authority or the Central Licensing Authority, as the case may be, of the occurrence of any suspected unexpected serious adverse event and action taken thereon including any recall within fifteen days of such event coming to the notice of licence holder. Field Safety Corrective Action Form (FSCA) can be used to notify the regulatory body about any action taken by a manufacturer to reduce a risk of death or serious deterioration in the

- The return of the medical device to its manufacturer;
- Replacement or destruction of the medical device;
- Any action regarding the use of the medical device that is taken in accordance with the advice of its manufacturer;
- The clinical management of any patient who has used the medical device;
- The modification of the medical device;
- The retrofitting of the medical device in accordance with any modification to it or any change to its design by its manufacturer;
- The making of any permanent or temporary change to the labelling or instructions for use of the medical device; or
- Any upgrade to any software used



FIELD SAFETY CORRECTIVE ACTION NOTIFICATION (FSCA) FORM

1. Before filling this form, the reporter collects and collates the prescribed information in the form.
2. This form will serve as the reporting tool in lieu with the Medical Devices Rules, 2017.
   Fourth Schedule
   [See rule 20(2), 21(2), 34(2), 63(1) and 64(1)] Part II (ii) (b) and Appendix II for intimating, notifying CDSCO for any Field Safety Corrective Action (FSCA) in relation to medical device product recall and other corrective action.
3. A scanned signed copy of PDF version of this form is to be sent to CDSCO via email to dci.nic.in
4. Additional information that may be pertinent for the completion of this form can be provided as an attachment.
5. All the field safety notices will be published on the CDSCO website and the reporter holds the full responsibility for the information contained in the Field Safety Notification and reporter must indemnify CDSCO for all losses, claims, demands, liabilities, causes of action, expenses of any kind arising from CDSCO's publication of the FSN.

Primary Information		
1.	**Type of Field Safety Corrective Action (FSCA)**	☐ Product Recall
		☐ Other Corrective actions
2.	**Type of Report**	☐ Notification
		☐ Preliminary Report
		☐ Final Report
3.	**Date of Report (dd/mm/yy)**	
4.	**Reference Number (auto generated by system)**	
Particulars of Reporters		
1.	**Contact Person Name**	
2.	**Job Title**	
3.	**Telephone Numbers**	
4.	**Email Address**	
5.	**Office Address**	
6.	**Local Contact Details (if reporter not based in India)**	

Notify changes through FSCA

MDR 2017 classifies changes as either Major or Minor. Depending on the type of change, pre-approval may be required before the change is implemented (in case of Major changes) and simply a notification (in case of Minor changes). This changes can also be notified through Field Safety Corrective Action form (FSCA). Type of changes and their categorization are specified under the Sixth Schedule as :-

MAJOR CHANGE

1. Change in material of construction
2. Change in design that shall affect quality in respect of its specifications, indication for use, performance, and stability of the medical device
3. Change in intended or indication for use
4. Change in method of sterilization
5. Change in approved shelf life
6. Change in name or address of manufacturing site
7. Change in name or address of authorized agent
8. Change in label excluding font size, type, color, label design

MINOR CHANGE

1. Change in design that shall not affect quality in respect of its specifications, indication for use, performance, and stability or the medical device
2. Change in manufacturing process, equipment, or testing that shall not affect quality of the device
3. Packaging specifications excluding primary packaging material

www.ipc.gov.in

Toll Free No. : 1800 180 3024

NCC-PvPI IPC

@IPC NCC-PvPI

mvpi.ipcindia@gmail.com

ADR Mobile-app

Helpline : 1800 180 3024

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 lives