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IPC

Guidance Document

Materiovigilance Programme of India (MvPI)

Version 1.2

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FOREWORD

Ministry of health and family welfare, Government of India has approved the commencement of Materiovigilance Programme of India (MvPI) at Indian pharmacopoeia commission on July 6, 2015 to monitor the safety of medical devices in the country. Indian Pharmacopeia Commission is functioning as National coordination center for MvPI and various steps and strategies have been made by NCC including launching of reporting tools to report MDAE, enrollment of new Medical Device Adverse Events Monitoring Centers and many others are in pipeline.

Training and workshops are organized in different regions of the country to improve the adverse event reporting practice and the attitude of healthcare professionals. NCC in collaboration with Central Drug Standard Control Organization, National Health System Resource Centre and Sree Chitra Tirunal Institute for Medical Sciences and Technology provides training and technical support to the stakeholders and this guidance document will be an important tool for conducting Materiovigilance activities. We are hopeful that this document will support to ensure the safety and efficacy of medical devices in the country by illuminating various components of MvPI.

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The word vigilance as per Oxford dictionary means — the action or state of keeping careful watch for possible danger or difficulties. All medical devices carry certain level of risk. Materiovigilance envisage close monitoring of any undesirable performance or characteristics fluctuations of a medical device by means of a system which is capable of identifying, collecting, reporting with estimate of undesirable occurrences and reacting to them with field safety corrective actions or device recall during post-marketing phase of a medical device.

a) **Programme objective**

To improve the protection of the health and safety of patients, healthcare professionals and others by reducing the likelihood of reoccurrence of an adverse event associated with the use of medical devices.

b) **Definition of medical device**

As per WHO, 'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in-vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury
- investigation, replacement, modification, or support of the anatomy or of a physiological process
- supporting or sustaining life
- control of conception
- disinfection of medical devices
- providing information by means of in-vitro examination of specimens derived from the human body
- aids for persons with disabilities
- devices incorporating animal and/or human tissues

- devices for in-vitro fertilization or assisted reproduction technologies
- disinfection substances;
- and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means

As per MDR, 2017, 'Medical device' means –

- Substances used for in vitro diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant covered under sub-clause (i) [all medicine for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals including preparations applied on human body for the purpose of repelling insects like mosquitoes]
- Substances including mechanical contraceptives (condoms, intrauterine devices, and tubal rings), disinfectants and insecticides notified in the Official Gazette under sub-clause (ii) [such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermins or insects which cause disease or disorder in human beings or animals, as may be specified from time to time by the central government],
- Devices notified from time to time under sub-clause (iv)[such devices intended for internal or external use in the diagnostics, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government], of clause (b) of section 3 of the Act;

c) Background

After several horrific cases associated with malfunctioning of medical devices like infants burnt to death due to short circuits in incubators, or hip implants causing blood poisoning, the Ministry of Health and Family Welfare (MoHFW), Government of India have approved Materiovigilance Programme in an effort to address potential adverse events related to medical devices. In addition to creating database on medical device adverse event, Materiovigilance programme will give insight to reduce likelihood reoccurrence of adverse events related to medical device elsewhere thereby improving medical device quality by and large. Materiovigilance Programme of India was launched by DCG (I) on 6th July 2015 at Indian Pharmacopoeia Commission, Ghaziabad. For Materiovigilance Programme of India (MvPI), Indian Pharmacopoeia Commission (IPC) functions as National Coordination Centre (NCC). Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), Thiruvananthapuram shall act as National Collaboration Centre, National Health System Resource Centre (NHSRC), New Delhi, shall act as Technical support partner and Central Drugs Standards Control Organization (CDSCO), New Delhi, shall support MvPI with experience of functioning as National regulator.

Materiovigilance Programme of India (MvPI) aims to collect data on medical device related adverse events systematically and scientifically analyze them to aid in regulatory decisions and recommendations on safe use of medical devices being made using data generated from India. The programme is meant to monitor medical device-associated adverse events (MDAE), create awareness among healthcare professionals about the importance of MDAE reporting in India and to monitor the benefit-risk profile of medical devices. It is also meant to generate independent, evidence-based recommendations on the safety of medical devices and to communicate the findings to all key stakeholders.

National Coordination Centre

Indian Pharmacopoeia Commission (IPC) is an autonomous institution of the Ministry of Health and Family Welfare, Govt. of India, and functions as National Coordination Centre for Materiovigilance Programme of India. The main responsibility of NCC is to monitor all adverse events of medical devices being observed in Indian population. NCC operates under the supervision of a steering committee and a working group which recommend procedures and guidelines for regulatory interventions. IPC also sets standards for drugs that are manufactured, sold and consumed in India. It also publishes Indian Pharmacopoeia and National Formulary of India to improve quality of medicine and promotes rational use of medicine.

National Collaborating Centre

Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) functions as National Collaborating Centre for Materiovigilance Programme of India. SCTIMST metamorphosed into an Institute of National Importance with the status of a University in 1980 under the Department of Science and Technology, Govt. of India, by an Act of Parliament. The joint culture of medicine and technology that the Institute pioneered more than three decades ago has come of age and gained unprecedented acceptance in India. The Institute focuses on patient care of high quality, technology development of industrial significance and health research studies of social relevance. The emphasis is on development of facilities less readily available elsewhere in the country such as interventional radiology, cardiac electrophysiology, pre-surgical evaluation and surgery for epilepsy, microsurgery and deep brain stimulation for movement disorders, new biomedical devices and products, evaluation of medical devices to global specifications, new academic programmes and global public health networks.

The Biomedical Technology Wing (BMT Wing) located at the Satelmond Palace in Poojappura, Thiruvananthapuram. The broad areas of activities of the wing include medical devices, Biomaterials, Biocompatibility, Tissue Engineering, Product

incubation and commercialization. Technical research centre for Biomedical devices (approved by the DST, Govt of India) is a nodal centre undertaking Five Programmes for Mission Mode Industrial R&D in areas of Cardiovascular devices, Neuro-prosthetic devices, Hard tissue devices, In- vitro diagnostics and Biological and combinational products.

Technical Support and Resource Centre

Technical support for the programme will be sought from institutions that have established technical capacity in the field of medical devices. To begin with, technical support will be taken from National Health System Resource Centre (NHSRC) which has been set up under the National Health Mission (NHM), Ministry of Health & Family Welfare, Government of India. The Healthcare Technology Division of NHSRC is a World Health Organization Collaborating Centre for Priority medical devices & Health Technology Policy. This division shall act as a technical support and resource centre for the Materiovigilance Program of India in future, additional technical support centre may be added to provide technical support on specific issues identified by competent authority as and when required.

d) Scope of Guidance Document

The document intends to act as an information guide to all stakeholders to have general awareness. Following are some of the key stakeholders under MvPI:

- Professional staff at IPC, SCTIMST, NHSRC, CDSCO, MDMC and the whole citizens of India would serve as stakeholders of the programme
- Representatives of Medical Device Adverse Event Monitoring Centre across the country
- Policy makers at all levels of healthcare, particularly those concerned with medical device policy
- Under MvPI, the Staff of clinical establishments like clinicians, biomedical engineers/ clinical engineers, hospital technology managers, pharmacists, nurses, technicians can report medical device adverse events. Medical device manufactures/CDSCO-notified medical device manufactures/medical devices

importers traders can also report adverse events specific to their product to the National Coordinating Centre.

- Medical Technologists and medical devices Innovators associated with Research and Development

Mission

Safeguard the health of Indian population by ensuring that the benefits of use of medical devices outweigh the risks associated with its use.

Vision

To improve patient safety and welfare of Indian population by monitoring adverse events related to medical devices and thereby reducing the risk associated with use of medical devices.

Scope and Objectives

- To create a nation-wide system for vigilance on medical device related adverse event. Active system provide forum for encouraging adverse event reporting, proactive investigation, collecting risk-based information from global regulators and conducting reactive investigation. The database would enable data analysis in multiple ways
- To capture and record suspected medical device adverse events like death or serious deterioration in state of health, serious injuries and disability
- To identify and analyze new signal from the reported cases both via active as well as passive surveillance
- To analyze the benefit-risk ratio/risk analysis/causality assessment of medical devices
- To generate evidence-based information on safety of medical devices and medical generate device alert to regulator/healthcare professional
- To support regulatory agencies in the decision-making process on use of medical devices
- To communicate the safety information on use of medical devices to various stakeholders with an aim to minimize the risk

- To emerge as a national centre of excellence for Materiovigilance activities
- To collaborate with other national centers for the exchange of information and data management
- To create awareness among healthcare professionals about the significance of MDAE reporting
- To provide training and consultancy support to other national Materiovigilance centers across the globe

Short-term goals'

- To develop and implement Materiovigilance Programme in all over India
- To encourage clinicians, biomedical engineers/clinical engineers, hospital technology managers, pharmacists, nurses, technicians, medical-device manufacturers for reporting adverse events related to medical devices
- Compile adverse events reports, analyze and issue medical device reports to medical device regulator
- Voluntary registration of medical device manufacturers to:
  - Report adverse events to IPC-NCC
  - Undertake root cause analysis for deterioration or failure on any of their medical device and report to IPC-NCC
  - Report corrective or preventive action taken in regards to potential adverse events/near miss incidents/adverse events/recalls related to medical devices

Long-term goals

- To expand the Medical Device Adverse Events Monitoring Centre (MDMC) to all hospitals (Govt. & Private) and centers of public health programmes located across India

- To develop and implement electronic reporting system (e-reporting)
- To nurture reporting culture among healthcare professionals, biomedical engineers, medical device manufactures etc.
- To provide feedbacks and issue progress or status report to all individuals reporting adverse events using MvPI MDAE form.
- Issue medical device alert to general public or hospitals via email or text message
- Monitor the corrective action taken by the manufacturer in response to report submitted by Materiovigilance programme centre
- To support health system where in procurement of medical device is only undertaken after studying adverse events associated with medical device intended for procurement
- To make Materiovigilance reporting mandatory for medical-device manufacturers or their authorized representatives for marketing or sale of medical devices in India
- To make adverse event reporting of medical devices mandatory for all healthcare providers under Clinical Establishment Act

Committees under NCC

The following committees and panels have been constituted by MoHFW, Government of India, to give proper direction for efficient functioning of the programme

MvPI Steering Committee

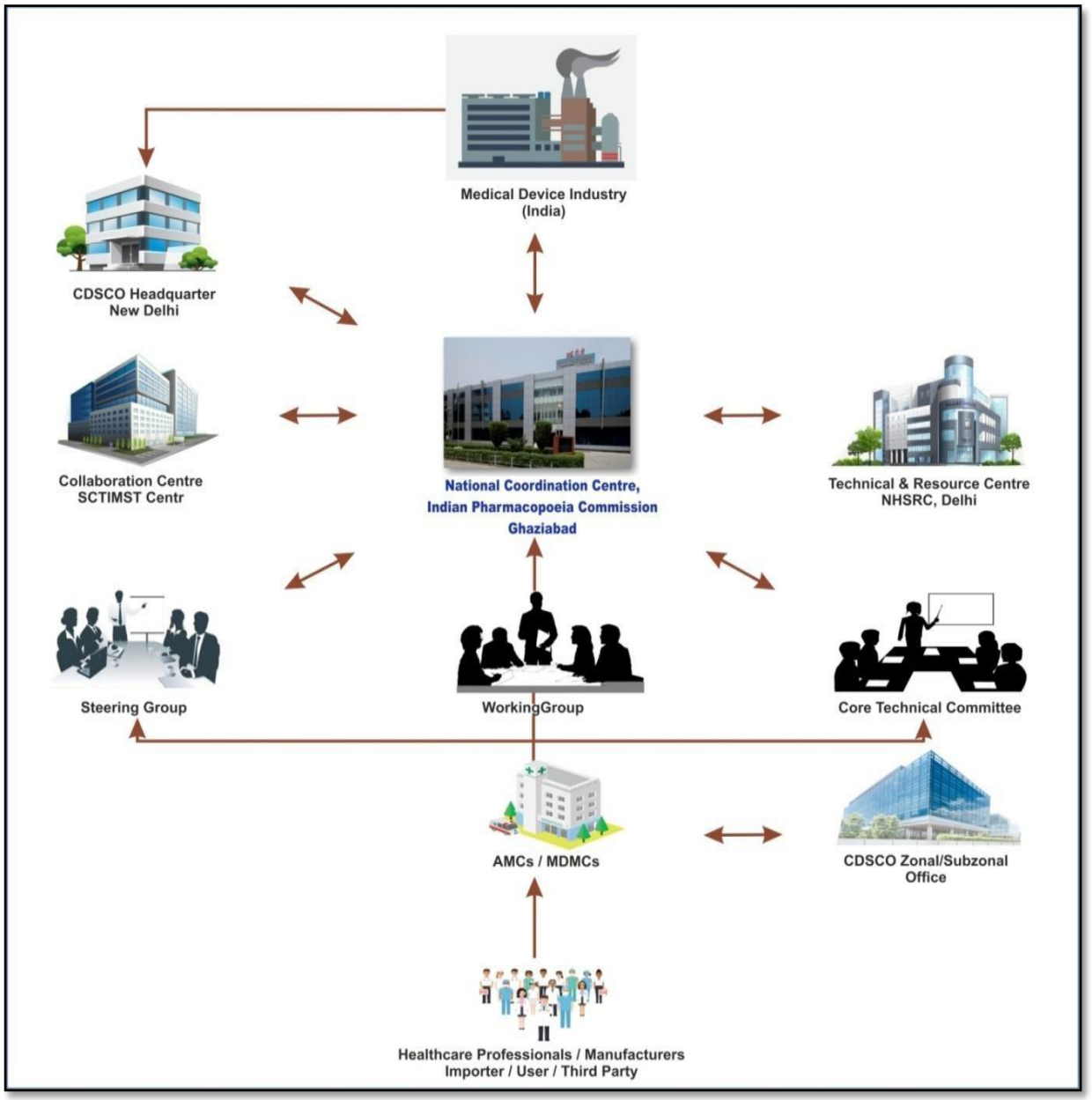
MvPI is administered and monitored by a Steering Committee for supervising and giving proper direction to the programme

MvPI Working Group

It has been constituted to approve major technical issues related to establishment and implementation of programme and giving technical inputs to CDSCO for regulatory intervention of medical devices. Working group may designate core technical committee for quality, technical, training and adverse event signal-related issues

Communication under MvPI

An effective communication channel is a key to successful functioning of MvPI. The following chart depicts the movement of information between the key stakeholders, ensuring continuous transfer of data, information and knowledge. Following figure shows the communication flow of MvPI.



Chapter 2 | Responsibilities of Stakeholders under MvPI

Personnel at Medical Device Adverse Events Monitoring Centre (MDMC)

Each MDMC under MvPI is assigned with a Coordinator and a Research Associate responsible for its functioning. Their roles and responsibilities are:-

- The designated Coordinator is responsible for proper functioning of the respective MDMC. In absence of the coordinator, the designated deputy coordinator is responsible for the smooth functioning of the centre. Standard operating procedure (SOP) for MDMC, Coordinator, MDMC-RA to be strictly adhered
- Other important responsibilities of the Coordinator include checking completeness of a valid case, failure mode effect analysis, causality assessment and scrutinizing the MDAE reports as per SOPs.
- Ensuring formation of Materiovigilance Expert Committee (MEC) and conducting timely meetings as and when required as per SOP. Coordinator should call for committee in MDMC after initial analysis for further deliberation with experts in MDMC centre as and when required.
- The Research Associate is responsible for collection and follow-up of MDAEs. All scrutinized and signed MDAE reports have to be sent for central assessment to National Collaborating Centre. MDAE report has to be submitted immediately after report preparation
- The Coordinator is responsible for sending the consolidated monthly reports of its MDMC to NCC
- In addition to reactive investigation or report preparation done by MDMC, proactive investigation and risk-based information from global regulators has to be reported as and when it's noticed
- The centre Coordinator is also responsible for sensitization/encouragement of clinicians, biomedical engineers, clinical engineers, hospital technology managers, pharmacists, nurses, technicians of the hospital for Medical Device Adverse Event reporting by various modes (e.g. lectures on MDAE reporting, emails, telephone communication, publication of pamphlets and newsletters)

- Feedback to all healthcare professionals involved in reporting is to be sent by the MDMC coordinator

Personnel at National Collaborating Centre (SCTIMST) are responsible for:

- Organizing continuous, professional development education programmes on Materiovigilance at various zone.
- Conducting periodic training and workshops for healthcare professionals at various zone.
- To provide research and development/testing support facility to the programme.
- To provide technical support in data analysis and release of medical device alert.

Personnel at National Coordination Centre (IPC) are responsible for:

- The main responsibility of NCC is to coordinate with all partners of the programme. Organizing steering committee and working group meetings
- Recognition of new Medical Device Adverse Event Monitoring Centers (MDMCs) of public and private hospitals across the country
- Recruitment of manpower and appointed MvPI staff shall work under the administrative control of IPC-NCC
- Any adverse event due to use of a medical device received directly at SCTIMST-NCC representative shall be immediately communicated to the nearest MDMC for further processing
- Recommend suspected medical device information to CDSCO for appropriate regulatory action
- Publication and dissemination of standard operating procedures, guidance documents, newsletters, training manuals, etc with technical support from NHSRC and SCTIMST
- Providing financial support to SCTIMST and NHSRC for procurement of technical document
- Providing assistance to NHSRC for organizing MvPI awareness programme among medical device manufacturers/healthcare organization.

Chapter 2 | Responsibilities of Stakeholders under MvPI

Personnel at Regulatory authority (CDSCO HQ) are responsible for:

- Taking appropriate regulatory decisions and action on the basis of recommendations made by IPC-NCC
- Joining International Medical Device Regulators Forum (IMDRF) and Asian Harmonization Working Party (AHWP) and other forums organized by regulatory body of other countries for exchange of post-market safety information globally via NCAR (National Competent Authority Report) form exchange programme
- Regular meetings with the NCC-MvPI, SCTIMST & NHSRC for continuing monitoring of medical device safety
- Auditing/inspecting MDMCs and National Collaboration Centre with IPC-NCC officials providing administrative support to run MvPI

Personnel at NHSRC are responsible for:

- To provide technical support/guidance for preparation of standard operating procedures, guidance documents, newsletters, training manuals, etc
- Support in Identification of new MDMC and intimating the same to IPC
- Technical support for National Collaboration Centre and National Coordination Centre activities, including training
- To draft terms of reference for various positions under MvPI. Explore possibility of integrating
- Data mining/data analytics to adverse event reports. Technical advice on setting up of online adverse events data collection and release of medical device alerts via Email/SMS, etc
- Awareness programme among medical device manufacturers/healthcare organizations

Chapter 3 | Post-Market Surveillance

The vigilance on use of medical devices, including collection of information on the quality, safety or performance of medical devices after the medical device is placed in market is termed as Post- Market Surveillance Programme. Another term for the same process is —Medical device Post- marketing surveillance or —medical device vigilance. Injury or death may not be necessarily being the final effect in a medical device associated adverse event. Final effect could be miss diagnosis or error in diagnosis, need of timely intervention from healthcare professional to prevent an adverse event that may lead to any harm/ injury to patient.

The objective of an adverse-event reporting system and its subsequent evaluation is to improve protection of health and safety of patients and users of the medical device, reducing the likelihood of the same type of adverse incident being repeated in different places at different times. This will be achieved by the evaluation of reported incidents, and wherever appropriate, dissemination of information which could be used to prevent such repetitions, or to alleviate the consequences of such repetitions.

The vigilance in medical devices is useful for:

Ministry of Health and Family Welfare, Government of India initiative on setting up a system to record and analyze medical devices related adverse events is a huge milestone in terms of providing secured, sensible and responsible healthcare to citizens in India.

The importance of an efficient system for dealing with medical devices safety risks and crises has become increasingly evident in recent years. Medical device safety issues tend rapidly to take on international significance. The speed with which information spreads in the modern world means that medical device safety concerns are no longer confined to individual countries.

Often the media and general public are informed at the same time as, or even before, the national regulatory authority. When crises arise, whether they are real or perceived, local safety issues or concerns arising abroad, regulatory authorities are expected to meet them openly, efficiently, thoroughly and rapidly.

Following are some of the key specific benefits to its stakeholders like Health system of India (Public & Private), National Regulator (CDSCO), Medical Device Manufactures, Healthcare professionals and citizens of India.

- Potential for huge reduction in direct cost (from Indian healthcare budget) related to preventable adverse events related to medical device
- Possible to contribute in optimization of medical device to maximum without compromising patient safety
- To contribute in establishing a system in India for systematic, scientific and practical means of screening large medical device adverse events datasets at national level
- Positive contributions to public health by identifying potential safety issues more quickly and/or more accurately than conventional passive responding to information on newspaper.
- To improve performance and promote patient safety through the identification of incidents that resulted in, or could have resulted in, patient harm. Subsequent investigation and analysis of the incidents including their severity, type, frequency, and probable cause, are intended to provide organizations with the necessary information to implement interventions that will limit recurrence of such events and mitigate their impact if they do recur.
- Medical device manufactures could put products in market with as sense of ethical business, analyze and improve design and performance of products.
- Better decision support for the medical device industry and National Regulator (CDSCO).
- Would result in establishing a open database system for healthcare professionals, healthcare procurement experts across country to procure medical devices with maximum value and weed out spurious products entering Indian Health systems.
- Adopting good Materiovigilance practice in clinical establishments and having an aptitude to utilize the advantages Materiovigilance solutions can provide key to unlock the power to maximize clinical safety returns in an evolving medical device technology.
- To provide supportive data to improvise product standards developed by ISO/BIS.A large number of adverse events occur due to the manufacturing defects in medical devices. There are various standards for testing the safety of medical devices, e.g. IEC 60601-1, first published in 1977 (referred to as IEC 601), addresses electrical, mechanical, temperature and fire- related hazards in medical devices. IEC 60601-1 has been further developed into Collateral & Particular Standards such as (IEC 60601-2-X) which are standards addressing

unique safety concerns for specific technologies used in medical devices, e.g. IEC 60601-1-3 for X-ray equipment. Some standards are device-specific such as IEC 60601-1-1 which address safety- related issues with only particular devices, e.g. IEC 60601-2-27 for ECG-monitoring devices.

For instance, IEC 60825-1:2014 standards ensure safety of laser products. Similarly, IEC 80601-2- XX and ISO 5840-3:2013 are standards for medical electrical equipment and active implantable medical device, respectively. Similarly, ISO 10993 entails a series of standards for evaluating the biocompatibility of medical devices. A wide range of standards is laid down by international organizations like ISO, ASTM, IEC and BIS to ensure safety of healthcare technology products

The adverse events include but are not limited to:

- Non-compliance or incomplete compliance to safety testing. Safety testing means proactive collection of information about the quality performance of medical device before placed in market. Post market surveillance requires safety testing for proactive collection or information about the quality and performance of medical device when they initially placed on market. E.g. Lot testing verification, its aim to identify any catastrophic product failure and to determine variation from lot to next lot.
- Non-declaration of sufficient warning/labeling even after testing based on objective standards labeling here refers in the use manual/instruction for users. E.g. a sterilizer sterilizes the instruments at certain label temp. 120°C as per user manual or instruction manual, if temperature falls above given temp i.e. 135°C than it leads to higher rate of adverse events.
- A higher rate of adverse events than what was declared in labeling after testing based on objective standards.
- Due to clinical application error: An act of commission or omission by the user or operator of a medical device which is not in accordance with the directions by the manufacturer
- An unintended use of medical device/equipment/instrument.
- A malfunction or deterioration in characteristics or performance. For IVDs where there is a

risk that an erroneous result would either (1) lead to a patient management decision resulting in an imminent life-threatening situation to the individual being tested, or to the individual's offspring, or (2) cause death or severe disability to the individual or fetus being tested, or to the individual's offspring, all false positive or false negative test results shall be considered as events.

- Unanticipated adverse reaction or unanticipated side-effect.
- Undesired interactions (electromagnetic interference, biocompatibility etc) with other substances or products.
- Inappropriate delivery of therapy.
- Degradation/destruction of the device (e.g. fire) examples of reportable adverse events are:
  - While taking an X-ray view of during patient examination, the C-arm had uncontrolled motion. The patient was hit by the image intensifier and his nose was broken. The system was installed, maintained, and used according to manufacturer's instructions
  - It was reported that a monitor suspension system fell from the ceiling when the bolts holding the swivel joint broke off. Nobody was injured in the surgical theatre at that time but a report is necessary (near miss incident). The system was installed, maintained, and used according to manufacturer's instructions
  - Loss of sensing after a pacemaker has reached end of life. Elective replacement indicator did not show up in due time although it should have as per device specification
  - Sterile single-use device packaging is labeled with the caution 'do not use if package is opened or damaged'. The label is placed by incorrect design on inner packaging. Outer package is torn and device is not used during procedure as device is stored with inner packaging does not offer sufficient sterile barrier
  - A batch of out-of-specification blood glucose test strips is released by manufacturer. Patient uses strips according to instructions, but readings provide incorrect values leading to incorrect insulin dosage, resulting in hypoglycemic shock and hospitalization
- Premature revision of an orthopedic implant due to loosening. No cause yet determined

Chapter 4 | Baseline Studies

Baseline studies could be conducted through a questionnaire(s) to capture data on potential medical devices adverse events based on Recalls/Filed safety correction notice issued by medical device regulators across the globe(e.g.: FDA, CE, Swiss medic, TPA-Australia etc). Though it is difficult to collect medical device-associated adverse events for all categories of devices, a beginning could be made by collecting those resulting due to medical devices categories that are put on alert by other international regulatory agencies. Baseline studies are essential as Materiovigilance Programme of India is in its initial stage and there are equipments in Indian market which are recalled by regulators across the globe but continue to be in use in India for want of materiovigilance enforcement. A sample questionnaire is given below for conducting initial studies. This sample questionnaire should be applied to all medical devices in the identified centers listed in Annexure Sample Questionnaire

1. **Health Facility demographics**

2. **Medical device information :**
   - a) Type of Device
   - b) Control/Lot/Serial No
   - c) Age of Device/Date of manufacture: (Indicates the number of years since the manufacturing date of the device)
   - d) How long was the device in use here: (Indicates how long the device was used)?
   - e) Packing condition sterile / Non sterile
   - f) Was the device tested during sale/installation?
   - g) If the device is meant for reuse: Is proper cleaning/maintenance done?

3. **Description of incident :**
   - a) Date of Incident
   - b) Patient Consequences: (Includes information on the effect of the event on patient, user or any other person(s) involved)
   - c) Details of Incident: (Includes description of device(s), equipment, or drug-device combination involved in the incident, and a detailed description of what happened in the incident)

4. **Medical Records Tagging :**

Data would be collected from medical records also to find more details of the incident and to triangulate the findings and increase validity of the data

5. **Baseline Causality :**

The research team would evaluate whether the event had any temporal relationship with the device, using different causality assessment criteria. This may include qualitative findings also like (a) action taken by manufacture with copy of final report (b) Does manufacture stick to timeframe mentioned in recall notice or field safety corrective notice (c) Medical device or equipment of different serial number or model number may also be observed to anticipate probable adverse events. Baseline studies also include documenting the correlation between the devices that are recalled by regulators in any country across the globe and the same model or type or category of medical device is sold in India, which could have the potential of causing an adverse event or a near-miss incident to Indian citizen.

6. **Timeframe and submission of report :**

d) The study has to be initiated when IPC –NCC or any other MDMC centre alerts about the recall or field safety corrective action notice issued by any medical device regulator across globe. The study has to be completed within 30 days from date of intimation and completed report has to be submitted to IPC-NCC

Chapter 5 | Reporting of Medical Device Adverse Events

In the pilot phase, reporting by a prescribed form would be done by research associates deputed at 39 Medical Device Adverse Event Monitoring Centers or voluntary medical device manufactures. The four-page format of the form is given at the end of chapter 5

Scenario where an event or incident is noticed by manufacturer or healthcare service-provider or MDMC. When an event or incident is noticed by medical device manufacturer Currently the incident or event reporting is to be taken as a voluntary initiative by medical device manufactures in India. When the manufacturer is aware of information regarding an event which has occurred with their device, manufacturers are advised to initiate investigation root cause for failure and intimate IPC-NCC. IPC-NCC would send this information to research associates at MDMC located nearest to location of event or incident.

The information obtained by performing device testing by the manufacturer, user or other party may include:

a) A malfunction or deterioration in the characteristics or performance of the medical device
b) An incorrect or out-of-specification test result
c) The discovery of a design flaw during design review
d) An inaccuracy in labeling, instructions for use and/or promotional materials. Inaccuracies include omissions and deficiencies. Omissions do not include the absence of information that should generally be known by the intended users
e) The discovery of a serious public health threat. This may include an event that is of significant and unexpected nature and is a potential public health hazard, e.g. Human Immunodeficiency Virus (HIV) or Creutzfeldt-Jacob Disease (CJD).
f) Increase in user error or application error with the medical device
g) Any other information (Recall or field corrective notice) made available by medical device regulators in other countries for the same product
h) Information available by way of literature, scientific documentation, or increase in complaint trend

It is possible that the manufacturer may not have enough information to decide definitively on the reporting of an event. In such a case, the manufacturer should make reasonable efforts to obtain additional information to decide upon reporting. Wherever appropriate, the manufacturer should consult the medical practitioner or healthcare professional involved, and try their utmost to retrieve the device concerned. As a general principle, there should be a pre-disposition to report rather than not to report in case of doubt on the reporting of an event when an event or incident noticed by Healthcare service-provider. The healthcare service-provider is aware of information regarding an event, which has occurred with their medical device. This information will be sent to research associates at the medical device event monitoring centers.

Assessing medical device associated with an event or incident

In assessing the link between the device and the event, the following parameters be followed:

- Opinion based on information made available by a healthcare professional
- Failure mode-effect and non-destructive root-cause analyses on the medical device
- Information concerning similar events in the past
- Complaint trends
- Other information made available by the manufacturer

A Committee may be formed at MDMC or at manufacture, as the case may be and then deliberate the initial findings on root cause of event. The committee formed at MDMC may have experts like research associate (prepared initial report and positioned at MDMC), MDMC coordinator, Biomedical/Clinical engineers, Administration/Quality official of hospital, Healthcare professional and/or technician handling medical device (added on ad hoc basis based on event or incident and medical device) associated with the use of medical devices. However, to make the correct assessment it may be difficult when there are multiple devices and drugs involved. In complex situations, it should be assumed that the device was associated with the event is minimally influenced by effect of drugs.

Chapter 5 | Reporting of Medical Device Adverse Events

Event or Incident not to be reported:

When the only root cause for the adverse event was that the device exceeded its service-life or shelf-life as specified by the manufacturer, and the failure mode is not unusual, the adverse event need not be reported.

Reporting under medical device vigilance systems is not usually required :

1. **When deficiency of a medical device found by the user prior to its use:**
   - Regardless of the existence of provisions in the instructions for use provided by the manufacturer, deficiencies of devices that are always detected (that could not go undetected) by the healthcare professional or end user, prior to its use do not need to be reported under the vigilance system.
   - This is without prejudice to the fact that the user should inform the manufacture of any deficiency identified prior to the use of a medical device.

   Examples :-

   - The packaging of a sterile single use device is labeled with the caution 'do not use if the packaging is opened or damaged'. Prior to use, obvious damage to the packaging was observed, and the device was not used.
   - Intravenous administration set tip protector has fallen off the set during distribution resulting in a non-sterile fluid pathway. The intravenous administration set was not used.
   - A vaginal speculum has multiple fractures. Upon activating the handle, the device fell apart. The device was not used.
   - A patient is admitted to hospital with hypoglycemia based on an incorrect insulin dosage following a blood glucose result. The investigation found that the test strip was used beyond the expiry date specified by the manufacturer

2. **When an inbuilt protection mechanism in medical device functioned correctly :**

   Events which did not lead to serious deterioration in state of health or death, because a

design feature protected against a fault becoming a hazard (in accordance with relevant standards or documented design inputs), do not need to be reported. As a precondition, there must be no danger for the patient to justify not reporting. If an alarm system is used, the concept of this system should be generally acknowledged for that type of product.

Examples :-

- An infusion pump stops, due to a malfunction, but gives an appropriate alarm (e.g. in compliance with relevant standards) and there was no injury to the patient.
- Microprocessor-controlled radiant warmers malfunction and provide an audible appropriate alarm. (e.g., in compliance with relevant standards) and there was no deterioration in state of health of the patient.
- During radiation treatment, the automatic exposure control is engaged. Treatment stops. Although patient receives less than optimal dose, patient is not exposed to excess radiation.
- A laboratory analyzer stops during analysis due to a malfunction of the sample pipetting module, but the appropriate error message was provided for the healthcare professional or end user. An intervention by the user or an immediate remote intervention by the manufacturer allowed the analyzer to resume the analysis, resulting in correct results.

3. **In case of an expected and foreseeable side effect associated with medical device:**

Cases which meet all the following criteria :

- clearly identified in the manufactures labeling;
- clinically well known (scientifically/clinically/ technically identified or declared during clinical trial or clinical practices) as being foreseeable and having a certain qualitative (Condition that lead to side effect cannot be numerically predicted) and quantitative predictability when the device is used and performs as intended;
- documented in the device master record, with an appropriate risk assessment, prior

to the occurrence of the event, and

- Clinically acceptable in terms of the individual patient benefit are ordinarily not reportable
- If the MDMC or Manufacturer detects a change in the risk-benefit-ratio (e.g. an increase of frequency and/or severity) based on reports of expected and foreseeable side effects that led or might lead to death or serious deterioration of state of health, this must be considered as deterioration in the characteristics of the performance of the device. A trend report must be submitted to the NCC (IPC) where the manufacturer or its representative has his registered place of business.

Examples :-

- A patient who is known to suffer from claustrophobia experiences severe anxiety in the confined space of a MRI machine which subsequently led to the patient being injured. Potential for claustrophobia is known and documented in the device product information.
- A patient receives a second-degree burn during the use in an emergency of an external defibrillator. Risk assessment documents that such a burn has been accepted in view of potential patient benefit and is warned in the instructions for use. The frequency of burns is occurring within range specified in the device master record.
- A patient has an undesirable tissue reaction (e.g. nickel allergy) previously known and documented in the device product information.
- Patient who has a mechanical heart valve developed endocarditic ten years after implantation and then died. Risk assessment documents that endocarditic at this stage is clinically acceptable in view of patient benefit and the instructions for use warn of this potential side effect.
- Placement of central line catheter results in anxiety reaction and shortness of breath. Both reactions are known and labeled side effects.

4. **In case of negligible likelihood of occurrence of death or serious deterioration of health due to event:**

   Where the risk of a death or serious deterioration in state of health has been quantified and found to be negligibly small need not be reported if no death or serious deterioration in state of health occurred and the risk has been characterized and documented as acceptable within a full risk assessment.

   If an event resulting in death or serious deterioration in state of health has happened, the event is reportable and a reassessment of the risk is necessary. If reassessment determines that the risk remains negligibly small compared to previous events of the same type, then there is no need to be reported retrospectively. Decisions not to report subsequent failures of the same type must be documented. Changes in the trend, usually an increase, of these non-serious outcomes must be reported.

Example :-

Manufacturer of a pacemaker released on the market identified a software bug and quantified the probability of occurrence of a serious deterioration in state of health with a particular setting to be negligible. No patients experienced adverse health effects

Severity of an adverse event can be broadly classified into three categories:

1. **Death of a patient, user of the device or other person**
2. **Serious injury to a patient, user or other person**

Serious Injury (also known as serious deterioration in state of health) is either a life-threatening illness or injury, permanent impairment of a body function, cause congenital abnormality or permanent damage to a body structure -- a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure. The interpretation of the term "serious" is not easy and should be made in consultation with a medical practitioner whenever appropriate

The term —"permanent or prolonged impairment" means irreversible impairment or

damage to a body structure or function, excluding minor impairment or damage. Medical intervention is not in itself a serious injury. It is the reason necessitating medical intervention that should be used to assess the reporting of an event.

3. **No Death or Serious Injury occurred but the event might lead to death or serious injury of a patient, user or other person, if the event recurs or not addressed or prevented within adequate time by healthcare professional. They are also termed as "Near Miss event".**

   All events do not lead to death or a serious injury. The non-occurrence of such a result might have been due to circumstances or to the timely intervention of healthcare personnel.

Who can Report

All healthcare clinicians, biomedical engineers, clinical engineers, hospital technology managers, pharmacists, nurses, HCP (Health Care Personnel), patients and technicians can report medical device adverse events (MDAEs). Medical device manufactures could voluntarily send adverse events specific to their product to IPC-NCC.

Why to Report?

As a healthcare professional or ethical medical device manufacturer, it is one's moral responsibility to report adverse events associated with use of medical devices, hence safeguard the health of public

What to Report?

To foster the habit of reporting, MvPI encourages reporting of all types of adverse events related to medical devices irrespective of whether they are known or unknown, serious or non- serious, frequent or rare though Materiovigilance is primarily concerned with adverse events associated with medical devices used in India

How and Whom to Report?

Use the Medical Device Adverse Event Reporting Form which is available on the official

website of IPC (www.ipc@gov.in) to report any adverse event. Reporters from MDMCs after filling the above mentioned MDAE reporting form can submit it to the coordinator or Research Associate of the respective MDMC. A reporter who is not part of MDMC can submit the filled MDAE reporting form to the nearest MDMC or directly to the National Collaborating Centre. Reporter can also mail the scanned form at lab.ipc@gov.in and copy to mvpi.ipcindia@gmail.com.

IPC having a facility of helpline number 1800-180-3024 to report adverse events associated with medical devices and medicines. A reporter can also call on this number to report MDAEs.

Timeframe for reporting an event or Incident:

Reporter	What to report	To Whom	When
Marketing authorization holder/ Manufacturers/ Importers/ Distributors	Any suspected unexpected serious adverse event incident like deaths, serious injuries, malfunction etc. and action taken thereon including any recall	• National Regulatory body • National Coordination Centre – IPC	Within 15 calendar days of becoming aware of an event.
User facilities	Death, serious injuries, malfunction etc.	• National Regulatory body • National Coordination Centre – IPC • Marketing authorization holder	Within 15 calendar days of becoming aware of an event. For non-serious events reporting to be done within 30 calendar days of becoming aware of an event.

MEDICAL DEVICE ADVERSE EVENT REPORTING FORM

Materiovigilance Programme of India (MvPI)

This form is intended to collect information on Medical Devices Adverse Event in India. The form is designed to be used by Manufacturer/Importer/ Distributor of Medical Devices, Healthcare Professionals and anyone with direct/indirect knowledge of Medical Devices Adverse Event.

Primary Information

1. Date of Report :
2. Type of Report : Initial ☐ Follow up ☐ Final ☐ Trend ☐
3. Reporter Reference No. :

Reporter Details

1. Type of Reporter : (a) Manufacturer ☐
   (b) Importer ☐ Healthcare Professional ☐ Others ☐ (specify).....
   Distributor ☐ Patients ☐
2. In case, where the reporter is not manufacturer, fill the following details:-
   (a) Has the reporter informed the incident to the manufacturer?
   Yes ☐ No ☐
   (b) Is the reporter also submitting the report on behalf of the manufacturer?
   Yes ☐ No ☐
3. Reporter contact information:
   a) Name :
   b) Address :
   c) Tel. /Mobile :
   d) Email :

Device Category

Medical Device	In Vitro Diagnostics (IVD)	Equipments / Machines
I. Therapeutic ☐ Diagnostic ☐ Both ☐	I. Kits ☐	I. Therapeutic ☐ Diagnostic ☐
II. Implantable device ☐	II. Reagents ☐	II. Therapeutic & Diagnostic ☐
Non-Implantable device ☐	III. Calibrator ☐	III. Imaging ☐
III. Single use device ☐	IV. Control Material ☐	IV. Invasive ☐ Non-Invasive ☐
Reusable device ☐	V. Others ☐	V. Others ☐
Reuse of manufacture marked Single use device ☐	VI. IVD electronic reader/ Analyzer ☐	
IV. Sterile ☐ Non Sterile ☐		
V. Personal use / Homecare use ☐		

Instruction for use Section A-F

- ***If Medical Devices/Equipments/Machines : Please fill all the sections i.e. A, B, C, D, E & F***
- ***If in Vitro Diagnostics (IVD) : Please fill sections i.e. A (except 6, 7, 8, 13, 14 & 16), B (except 1, 2, 6 & 8), D, E, & F***

(A) Device Description

Device Name / Trade Name / Brand Name:

Details	Name	Address	License No.
Manufacturer			
Importer			
Distributor			

1. a) Is the device notified/regulated in India : Yes ☐ No ☐

   b) Device Risk Classification as per India MDR 2017 : A ☐ B ☐ C ☐ D ☐
2. License No. :
3. Catalogue No. :
4. Model No. :
5. Lot / Batch No. :
6. Serial No. :
7. Software Version :
8. Accessories / Associated Devices :
9. GMDN Code & GMDN Term (If applicable) :
10. UDI No. (If applicable) :
11. Installation Date :
12. Expiration Date :
13. Last preventive maintenance date (dd/mm/yyyy) :
14. Last calibration date (dd/mm/yyyy) :
15. Age of device from date of manufacturing :
16. How long was device in use :
17. Availability of device for evaluation : Yes ☐ No ☐ If no, was the device

    Destroyed ☐ Still in use ☐ return to manufacturer or importer/distributor ☐
18. Is the usage of device as per manufacturer claim /Instruction for use/user manual: Yes ☐ No ☐

    If no specify usage .....
19. For devices not regulated / notified in India : Regulator / Regulatory status in country of origin

    .....

(B) Event Description

1. Date of Event / Near miss incident:
2. Date of Implant (If applicable):
3. Location of Event:

   Hospital Premise ☐ Manufacture/Distributor premise ☐

   Home ☐ Others ☐
4. Device Operator:-

   Healthcare Professional ☐ Patient ☐ Others ☐

   Problem noted prior to use/near miss event ☐
5. Device disposition / Current location:

   a) Returned to company ☐ If yes, date ……/……. /……

   b) Remains implanted in patient ☐

   c) Within the healthcare facility ☐

   d) At patient home ☐

   e) Destroyed ☐

   f) Others (specify) ☐

6. Serious event: ☐

   Tick the appropriate reason

   a) Death (DD/MM/YY) ☐ ……/……/……

   b) Life Threatening ☐

   c) Disability or permanent damage ☐

   d) Hospitalization ☐

   e) Congenital anomaly /birth defect ☐

   f) Any other serious (Imp. medical event) ☐

   g) Required intervention to prevent / permanent ☐

   Impairment / damage device
7. Non serious event: ☐
8. Is device in use after incidence: Yes ☐ No ☐

8. Detail description of Event:-

9. Frequency of occurrence of similar Adverse Event in India in past 3 years	Year	No. of Similar Adverse Events	Total No. Supplied	Frequency of Occurrence (%)
10. Frequency of occurrence of similar Adverse Event in globally in past 3 years	Year	No. of Similar Adverse Events	Total No. Supplied	Frequency of Occurrence (%)

(C) Patient Information, History & Outcome

1. Patient Hospital ID :
2. Patient Initial :
3. Age :
4. Sex : Male ☐ Female ☐ Others ☐
5. Weight :
6. Other relevant history, including pre-existing medical conditions……
   ……
   ……
   ……
   ……
7. Patient Outcomes:

   a) Recovered Date (DD/MM/YY) ☐ ……/……/……

   b) Not yet recovered ☐

   c) Death ☐ (DD/MM/YY) ☐ ……/……/……

   d) Others ☐ Please

   Specify……
   ……
   ……
   ……
   ……
   ……

(D) Healthcare Facility Information (if available)

1. Name :
2. Address :
3. Contact Person Name at the site of event :
4. Tel. No. :

(E) Causality Assessment

1. Investigation action taken :

2. Root cause of problem (Applicable for follow up / final reports):

(F) Product Owner's Investigation & Action taken

1. Product Owners device risk analysis report:

2. Corrective / preventive action taken:

3. Device history review:

Where to report?

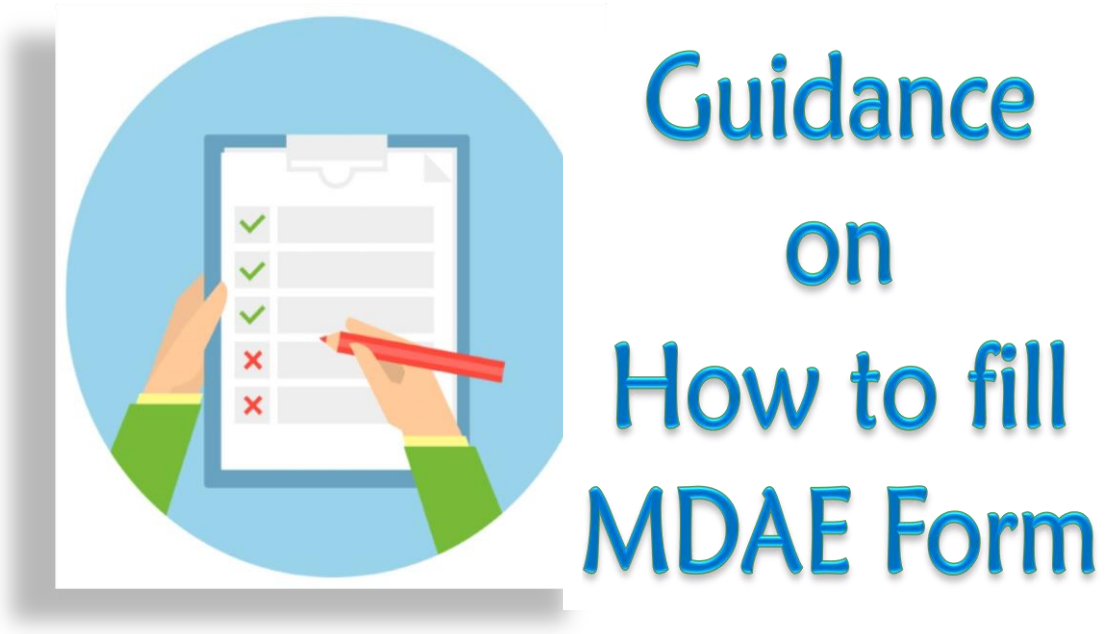
Duly filled Medical Device Adverse Event Reporting Form can be send to Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare, Government of India, Sector-23, Rajnagar, Ghaziabad-20002, Tel-0120-2783400, 2783401 and 2783392, FAX:0120-2783311 or email to mvpi.ipcindia@gmail.com Or Call on Helpline no. 1800 180 3024 to report Adverse event.

Partnering Organizations

Disclaimer

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the adverse event.

Chapter 5 | Reporting of Medical Device Adverse Events



The following provides guidance on what information is required to fill the Medical Device Adverse Event reporting form.

GENERAL INFORMATION

Each field must be completed with the requested information, "NA" if not applicable, or "unknown" when the data is not known or available. If the space provided in the form is insufficient, please provide the information in extra space provided on pg. number 5

For online version

https://www.ipc@gov.in/images / MEDICAL DEVICE ADVERSE EVENT REPORTING FORM editable.pdf

You may also provide the "Additional information" at the end of the form as an attachment to provide any additional details that are relevant and not requested elsewhere.

- **Date of Report :** It is the date on which the event is reported to IPC-NCC-MvPI/MDMC/AMC Report type.
- **Initial :** The first report that the reporter is submitting about an event.
- **Follow-Up :** Additional information to a previous (initial or follow-up) report.

- **Final :** The last report that the reporter expects to submit about an event. The initial report can be a final report if the reporter has all the information about the event.
- **Trend :** Significant changes in frequency of occurrence or severity of events associated with devices must be reported. These reports are called trend reports.
- **Reporter Reference No. :** The reference number assigned by the MDMC/ Manufacturer/Authorized Representative.

REPORTER INFORMATION

- **Type of Reporter :** Select whether the type of reporter is manufacturer/ importer/ distributor / healthcare Professional / patient or others (If others, please specify). If the reporter is not the manufacturer, fill whether the information is being informed to the manufacturer besides reporting to NCC- MvPI or is reported on behalf of the manufacturer.
- **Reporter Contact information :** Fill the reporter's information such as name, address, contact number and e-mail.

DEVICE CATEGORY

- **Medical Device :** select the boxes given according to usage of medical device.
- **In Vitro Diagnostic (IVD) :** select the boxes given for in-vitro examination of specimens derived from the human body.
- **Medical Equipment :** select the boxes according to usage of medical devices which require regular maintenance, calibration and commissioning/decommissioning activities.

A. DEVICE DETAILS

- Device Name/Trade Name/Brand name: Indicate the brand or trade name of the affected device.
- Fill the name and address of manufacturer, importer and distributer.
- Fill the regulatory status of device along with other details e.g. device risk classification (If known to consumer, mandatory for manufacturer, importer & distributor), license no. (manufacture/import), catalogue no., model no., lot/batch no., serial no., software version, associated devices/accessories, nomenclature code (if applicable);

GMDN/UMDN (Global Medical Device Nomenclature Code and explanatory term), UDI no. (if applicable), installation date, expiration date, last preventive maintenance/ last calibration date, year of manufacturing, how long was device in use and availability of device for evaluation. For devices not regulated in India, fill the regulatory status in country of origin.

B. EVENT DESCRIPTION

- Fill the date on which event was occurred and date of implant or explants (if applicable).
- Select the boxes to choose appropriate location of event, operator of concerned medical device at the time of adverse event.
- Device disposition/current location: Where and in what state the device is at the time of the report e.g. destroyed, returned to manufacturer or within the health care facility
- Serious event: Select this category when the adverse event results in the death, life threatening, caused disability or permanent damage, hospitalization or prolongation of hospitalization, any birth defect or serious deterioration in state of health of a patient, user or other person.
- State the name and uses of other medical devices, which were used with reported medical device at same time.
- Detail description of event : Give a detail description of adverse event.
- Section 11 & 12 (for manufacturer or authorized representative only) report the frequency of occurrence of similar adverse event during last three years in India and globally.

C. PATIENT INFORMATION, HISTORY & OUTCOME

- Fill patient's hospital Id (given by hospital), initial (e.g. If patient name is Rajesh, then initial is RAJ), age, gender, weight and other relevant medical history.
- Provide the patient's outcome details e.g. recovered, not recovered, death etc.

D. HEALTHCARE FACILITY INFORMATION

- Fill the healthcare facility information, where adverse event occurred such as name, address and contact details of person at the site of event.

E. CAUSALITY ASSESSMENT

- Investigation Action Taken: Specify details of investigation methods carried out by the clinical specialists at healthcare facility or manufacturer. Immediate action taken to rectify the adverse effect if possible should be included. If no investigation is to be done, a rational needs to be provided here.
- Root cause of problem: State the root cause that would ascertain the most likely reason why the problem occurred with the medical device.

F. MANUFACTURER/AUTHORIZED REPRESENTATIVE INVESTIGATION & ACTION TAKEN

(Applicable to Manufacturer/Authorized Representative only)

Manufacturer/Authorized Representative device risk analysis report: Specify, for this event, details of investigation methods, results and conclusions. The rationale for the course of action taken to investigate the incident should be included. The details of the actions to be completed and the timelines for their completion should be included. If no investigation is to be done, a rational needs to be provided here. The root cause should be identified. The root cause would ascertain the most likely reason why the problem occurred with the medical device. This may not be available at time of reporting.

Corrective/Preventive Action taken: Includes information on actions taken to correct the problem, including any post-market surveillance, recalls, or corrective or preventive actions and the design and manufacture of the device. This should also include the rationale for performing the corrective action. If no corrective action is to be taken, a rationale needs to be provided here. This may not be available at time of reporting.

Device History Review: Includes a review of other similar events involving the same lot/batch, It should also include a review of device history records for each batch, lot or unit to ensure that the device was manufactured according to specifications, no anomalies during the manufacturing process etc.

Chapter 6 | Causality Assessment

Causality assessment measures the relationship between the use of a medical device and the occurrence of any adverse event and their categorization. Causality is referred to the expression of the strength of association of a medical device with a suspected adverse event. The main aim of causality assessment is to produce this expression of association in a standardized, transparent and rational manner with the application of qualitative and/or quantitative methods.

The causality assessment helps as follows: -

a) It decreases disagreement between assessors by establishing a standardized approach.
b) It will classify likelihood of relationship.
c) It will mark individual case reports.
d) It helps in improvement of scientific and educational evaluation.

However, the process of causality assessment may have the following limitations:-

a) It cannot give a very accurate quantitative measurement of likelihood of relationship.
b) It cannot always distinguish valid from invalid cases.
c) It cannot change uncertainty into certainty.
d) It cannot quantify the contribution of device to the development/occurrence of event.

Since assessment of causality is undertaken for reported events, it is necessary to ensure a standardized report that meets certain pre-specified quality and content assurance criteria. The following serves as themes to capture the important criteria within an adverse event reports:-

a) Quality check for completeness of a reported case.
b) Validity of the case.
c) Follow up a case, if necessary.

CAUSALITY ASSESSMENT

This level of causality assessment has to be done by casualty assessment committee members deputed at 50 Medical Device Adverse Event Monitoring Centers (MDMCs) in collaboration with the National Collaborating Centre, SCTIMST and IPC-NCC.

Chapter 6 | Causality Assessment

OVERVIEW OF CAUSALITY ASSESSMENT PROCEDURE

The causality assessment activity has to be a combination of clinical investigation, risk-management analysis and failure-analysis including, but not limited to, Material, Mechanical, Electrical, Electronic, Biocompatibility software, etc. Causality assessment based on clinical investigation will be conducted on the basis of ISO 14155. Risk-management analysis will be done as per ISO 14971 and similarly failure mode-effect analysis.

An adverse event can be related to both procedures and the investigational device. Complications of procedure are considered 'not related ', as the said procedures been applied to patients in the absence of investigational device use/application. In some particular cases the event may not be adequately assessed because information is insufficient or contradictory and/or the data cannot be verified or supplemented. The investigators will put in the maximum effort to define and categorize the event and avoid such complications. The categories of Causality Assessment is given below-

CAUSALITY CATEGORIES	
Causality Term	Assessment Criteria
Not related	- the event is not a known side effect of the product category the device belongs to or of similar devices and procedures, generally is considered "not related". Yet, the unexpected effect shall not be excluded from evaluation and reporting; - the event has no temporal relationship with the use of the investigational device or the procedures; - the serious event does not follow a known response pattern to the medical device (if the response pattern is previously known) and is biologically implausible; - the discontinuation of medical device application or the reduction in the level of activation/exposure - when clinically feasible - and reintroduction of its use (or increase of the level of activation/exposure), do not impact on the serious event;

	- the event involves a body-site or an organ not expected to be affected by the device or procedure; - the serious event can be attributed to another cause (e.g. an underlying or concurrent illness/clinical condition, an effect of another device, drug, treatment or other risk factors); - the event does not depend on a false result given by the investigational device used for diagnosis, when applicable; - harms to the subject are not clearly due to use error; - In order to establish the non-relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the serious event.
Unlikely	The relationship with the use of the device seems not relevant and/or the event can be reasonably explained by another cause, but additional information may be obtained.
Possible	The relationship with the use of the investigational device is weak but cannot be ruled out completely. Alternative causes are also possible (e.g. an underlying or concurrent illness/clinical condition or/and an effect of another device, drug or treatment). Cases where relatedness cannot be assessed or no information has been obtained should also be classified as possible.
Probable/likely	The relationship with the use of the investigational device seems relevant and/or the event cannot reasonably explained by another cause, but additional information may be obtained.
Causal relationship	the serious event is associated with the investigational device or with procedures beyond reasonable doubt when: - the event is a known side-effect of the product category the device belongs to or of similar devices and procedures; - the event has a temporal relationship with investigational device use/application or procedures;

	- the event involves a body-site or organ that - the investigational device or procedures are applied to; - the investigational device or procedures have an effect on; - the serious event follows a known response pattern to the medical device (if the response pattern is previously known); - the discontinuation of medical device application (or reduction of the level of activation/exposure) and reintroduction of its use (or increase of the level of activation/exposure), impact on the serious event (when clinically feasible); - other possible causes (e.g. an underlying or concurrent illness/ clinical condition and/or an effect of another device, drug or treatment) have been adequately ruled out; - harm to the subject is due to error in use; - the event depends on a false result given by the investigational device used for diagnosis, when applicable; - In order to establish the relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the serious event.
Un-assessable	- Report suggesting an adverse event - Cannot be judged because information is insufficient or contradictory - data cannot be supplemented or verified

Research associates and MDMC coordinators during their scheduled training will be taught the detailed procedure for conducting failure mode-effect analysis on medical devices. Similarly, the techniques used for root-cause analysis on the failure of medical devices and the necessary details need to be incorporated in the final causality assessment report by the MDMC.

*Causality categories are adopted from European Directives 90/385/EEC and 93/42/EEC and WHO-UMC system for standardized case causality assessment.

Chapter 7 | Signal Detection

There is a striking difference in signal detection as practiced in drugs and as suggested for devices. The reason: most pharmaceutical products have a single or at the most a dual Active Pharmaceutical Ingredient (API). A single device could, however, have hundreds of components, each working on a distinct technological pathway. Signal detection in medical devices could make root-cause analysis more elaborate.

Signal detection involves identifying patterns of adverse events associated with a particular device that warrant further investigation.

A medical device safety signal may arise from: -

- a previously unrecognized safety issue
- a change in frequency or severity of a known safety issue
- identification of a new at-risk group
- use of a device other than one intended by the manufacturer

Based on the completed root cause analysis report, events/incidents would be classified as per above mentioned signals or classification of signals after discussion in core technical committee of MvPI. Signals would be used as markers for trend analysis.

As soon as a safety signal has been detected, it is assessed to determine the nature, magnitude and significance of the concern, and the impact on the overall benefit-risk profile of the device. The complete analysis of the signals detected has to be initiated after getting enough adverse events reports.

Chapter 8 | Regulatory Action & Action Outcome on Medical Device Ecosystem

The regulatory structure has an established licensing component, a proactive inspection component and a responsive compliance/investigation component. The licensing component plays a major role in pre-market approval and device registration. Post-market surveillance, including a responsive investigational component, is in a nascent stage in India. Support of clinical engineering apart from other sciences within medical faculty could play a significant role in regulating medical devices by post-market surveillance.

Timeframe for recall: The speed with which the various elements of the recall are to be accomplished have to be clearly addressed in the recall strategy. Where the initial communication is not the corrective action, a detailed plan including estimated timeframes for accomplishing the corrective action needs to be included in the recall strategy. This has to be based on the rationale which takes into account factors such as complexity of the fix, number and geographic location of customers, the risk associated with the affected device, validation requirements, and continuous availability of essential products.

Severity associated with the device intended for recall:

Severity associated with recall has to be classified on the basis of the health hazard. Health hazard may be classified as:

Type I: A situation in which there is a reasonable probability that the use of, or exposure to, a recalled device will cause serious adverse health consequences or may even result in death.

Type II: A situation in which the use of, or exposure to, a recalled device may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote.

Type III: A situation in which the use of, or exposure to, a recalled device is not likely to cause any adverse health consequences. Such hazard-based classification systems can be formulated in countries intending to initiate a Post-Market Surveillance Programme.

Effectiveness checks by the recalling Manufacturer:

The purpose of effectiveness checks is to verify that all organizations (Manufacturer/importer- trader/distributor, etc) specified in the regulatory strategy has received notification about the recall and has taken appropriate action. The method for contacting may be accomplished by personal visits, telephone calls, letters, or a combination thereof. The recalling firm is responsible for conducting effectiveness checks.

Records generally include:

- Dates of attempted contact.
- Response received at each attempt.
- Name and title of person contacted.
- Means of contact, including telephone or fax number, email or mailing address.
- Details of communications once contact is successful.
- Conclusion as to whether recall instructions were understood and carried out.

A recall progress report should normally contain the following:

- Number of organizations (Manufacturer/import-trader/distributor, etc) notified of the recall and date and method of notification
- Number of respondents and quantity of affected device(s) in possession of each
- Number of non-respondents
- Number of devices returned or corrected and the quantity of devices accounted for
- Number and results of effectiveness checks
- Estimated timeframe for completion if revised from the original

Design Considerations to reduce recall/corrective action:

The complexity and diversity of medical devices used simultaneously contribute to human factor/error. A key objective of human factor in medical device design is to enhance the likelihood of good performance under less-than-ideal conditions. To minimize human

factor/error, devices should be designed according to users 'needs, abilities, limitations, and work environment. This includes the design of the device's user-interface, which includes controls, displays, software, labels, and instructions — anything the user may need to operate and maintain a device

Good design should include:

- operation that's intuitive and doesn't require frequent reference to an instruction manual.
- Easy-to-read displays.
- Easy-to-use controls.
- Appropriate connections of device-to-device and device-to-outlet for safe use.
- Effective alarms.
- Easy repair and maintenance.

Significance of training to reduce recall/corrective action:

It is important that anyone using a device has received training for operating it. Then consider a less obvious factor, the user's expectations of how the device works. Whether a user is a healthcare professional or a patient, he/she may expect a device to work like another device that looks similar. For example, based on his/her experience, he/she may expect a device to deliver the same prescribed treatment or dose as a similar device, or expect the alarms to be in a specific sequence or pattern of sounds.

Many intra-venous (IV) fluid pump programming errors were reported when the actual device function wasn't what the user expected. It is important that healthcare providers, manufacturers, importers and distributors are also trained according to regulations covering the adverse event reporting system.

Appropriate Communications/awareness to reduce adverse events:

Monitoring, evaluating and communicating device safety is a public health activity with

profound implications for the public at large. Consumers, health professionals, clinical engineers/biomedical engineers, researchers, academia, media, pharmaceutical industry, device regulators, governments and international organizations need to work in tandem to achieve the objective of safety of health for all. Scientific, ethical and professional standards bound by a moral code would govern this activity. The inherent uncertainty of risks and benefits of devices needs to be acknowledged and explained. Decisions and actions that are based on this uncertainty should be informed by scientific and clinical considerations and should take into account social realities and circumstances (Adapted from Preamble of the Erice Declaration Effective Communications in Pharmacovigilance 1997)

Conclusion:

Given that many countries do not have a Post-Market surveillance/vigilance programme; it is desirable that a beginning is made. Although it is a complex science in itself which requires the support of many domains including clinical medicine as well as clinical engineering/biomedical engineering. These required capacities exist in many countries to promote safer use of medical devices for the maximum health benefit to the patients as well as care providers.

Chapter 9 | Field Safety Corrective Action Form

The field safety corrective action (FSCA) notification form is developed to notify the regulatory authority and the consignees regarding any corrective action or recall that has been initiated by the manufacturer to reduce any serious adverse reaction associated with the use of medical devices. This notification form can be submitted by the manufacturer or the authorized representative on behalf of the manufacturer. The format of the form is given at the end of chapter 9.

The FSCA includes (i) device returned to the manufacturer (ii) device design changes (iii) device software up-gradation (iv) labeling changes (v) changes in instructions for use or directions for use or technical manual (vi) device destruction (vii) device exchange.

The FSCA includes three types of report (a) Preliminary (b) Follow up / Final (c) Notification. Preliminary FSCA notification includes reason for the FSCA, FSCA strategy (if affected stock have been supplied in India), authorized representative's health hazard evaluation, authorized representative's root cause analysis , authorized representative's corrective action/preventive action to reduce likelihood of recurrence of device issue, affected device status, including; list of affected consignees, number of affected units per local consignee, quantity manufactured/imported/supplied in India, for manufactured devices that have been exported; list of countries exported to and quantity of affected units exported shall be provided to the national regulatory authority, authorized representative's field safety notice (FSN) or other risk communication documents, a draft letter to intimate healthcare professionals regarding the FSCA or print advertisement.

Follow up / final FSCA notification includes an update on progress of the reconciliation of stock affected by the FSCA, together with confirmation that the consignees have received the FSN. It should also provide a progress report on the investigation to date and any additional CAPA that is being considered by the manufacturer or authorized representative, authorized representative's CAPA to reduce likelihood of recurrence of device issue, for recalled medical device, proof of return of recalled devices to the manufacturer should be included, declaration letter from the dealer on dealer's letterhead stating the completion of

field correction for affected consignees in India, consignee acknowledgement receipts confirming the receipt of the FSN, FSCAs that require a software upgrade or device modification, service reports for the completion of the corrective actions specified in the FSN or other risk communication documents.

Notification includes product owner's FSN or other risk communication documents, quantity imported but not supplied and/or present as stock in warehouse. The purpose for requesting this information is to verify and confirm that there has been no manufacture or supply of the affected devices in India, in the case of notified medical devices, the dealer shall ascertain whether there is a need for submission of a change notification for the medical devices corrected for the FSCA.

The FSCA notification will effectively enable the regulatory authority to take any regulatory interventions to prevent any harm to the patient related to medical devices.

Chapter 9 | Field Safety Corrective Action Form

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 Number(s)**	
4.	**Email Address**	
5.	**Office Address**	

6.	**Local Contact Details (if reporter is not from India)**	

Device General Information		
1.	**Device Name**	
2.	**Device Risk Classification as per MDR 2017**	
3.	**Accessories / Associated Devices Affected**	
4.	**Device Intended Use**	

Regulatory Details		
In India		
1.	**Device Regulatory Status**	Is the device registered in India ☐ Yes ☐ No
		Is the device marketed in India ☐ Yes ☐ No
		If yes provide details :
2.	**Manufacturer(s) and Contact Details**	
3.	**Product License Holder / Local Authorized Representative Name & Address**	
4.	**Importer(s) / Distributor(s) Contact Details**	
Other than India		
1.	**Device Regulatory Status**	Is the device registered globally ☐ Yes ☐ No
		Is the device marketed globally ☐ Yes ☐ No
		If yes provide details :

Impacted Device Information		
1.	**Model Number**	
2.	**Catalogue Number**	
3.	**Serial Number**	
4.	**Affected Lot / Batch Number**	

5.	**UDI Number (if applicable)**	

6.	**GMDN Code & GMDN Term (if applicable)**	
7.	**Accessories / Associated Devices Affected**	
Device Related to FSCA Information		
1.	**Number of affected Unit**	**Manufactured in India** Period : (mm/yyy) to (mm/ yyy) **Imported into India** Period : (mm/yyy) to (mm/yyy) **Supplied in India** Period : (mm/yyy) to (mm/yyy) **Expected Shipment to India** Expected Date of Arrival : (mm/yyy)
2.	**Number of affected units supplied to stakeholder(s)**	
3.	**Total Number of device recalled**	
3.	**FSCA Strategy**	
4.	**Did the FSCA arise due to an adverse event?**	☐ Yes ☐ No
5.	**If yes, what is the category of adverse event?**	☐ Serious Public Health Threat ☐ Death ☐ Serious Injury ☐ Non-Serious Injury
6.	**Did this adverse event occur in India?**	☐ Yes ☐ No If Yes then adverse event Ref. No. & Summary :
7.	**Evaluation of risk associated with affected device (Health Hazard Evaluation Report)**	
8.	**Give reason & detail for FSCA (if other than the adverse event)**	
Affected Device Details (e.g. device identifiers, lot/batch No.) listed in the FSCA Communication		
For India		
1.	**Affected device details**	
2.	**Has the FSCA communication been sent to all stakeholders?**	☐ Yes, Date Sent : (dd/mm/yyyy) ☐ No (dd/mm/yyyy) Expected Date to be sent :
3.	**Date of commencement of FSCA by product owner (dd/mm/yyyy)**	

4.	Date of commencement of FSCA in India (if applicable)	
5.	Countries to which FSCA has been reported (if any)	
6.	Proposed date of completion of FSCA (if applicable)	
7.	• Summary of root cause analysis	
	• Time taken for root cause analysis	
8.	Specify whether root cause was singular event or due to any problem in QMS	
9.	Summary of Corrective and Preventive Action (CAPA)	
For Other than India		
1.	Has the FSCA communication been sent to all stakeholders?	
2.	Date of commencement of FSCA by product owner (dd/mm/yyyy)	
3.	Date of commencement of FSCA (if applicable)	
4.	Countries to which FSCA has been reported (if any)	
5.	Proposed date of completion of FSCA (if applicable)	
6.	• Summary of root cause analysis	
	• Time taken for root cause analysis	
7.	Specify whether root cause was singular event or due to any problem in QMS	
8.	Summary of Corrective and Preventive Action (CAPA)	
Change Notification (if applicable)		
1.	Type of change (software change, design change, labeling)	

2.	**For software change, have any feature not related to FSCA incorporates**	☐ Yes ☐ No If Yes then provide details :
Other Information		

I attested that the information submitted is true and accurate and that I am authorized to submit this form in behalf of company.

Signature : ……

Name of reporting person : ……

Date of Notification : ……

GLOSSARY

Abnormal use/man oeuvre: Due to lack of experience and training, there may exist act/man oeuvre of omission of warning, provided from manufacturer against —"instructions of use". User error is, therefore, an act of commission or omission that has a result different to one intended by the manufacturer or expected by the operator. User error includes slips, lapses, mistakes and reasonably foreseeable misuse.

Active & Passive Surveillance: In passive surveillance, criteria are established for reporting diseases, risk factors or health-related events. Health practitioners are notified of the requirements and they report events as they come to their attention. This is the more common type of surveillance. Active surveillance, criteria are established for reporting disease (or its absence), risk factors or health events, but those maintaining the surveillance system active to initiate reporting. Active surveillance is used when there is an indication that something unusual is occurring.

Adverse Event: An adverse event (AE) is any untoward medical or technical occurrence with a medical device during operation with or without patient.

API: Active pharmaceutical ingredient (API) is any substance or combination of substances used in a finished pharmaceutical product, intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings.

ASTM: ASTM International is an international standards organization that develops and publishes voluntary consensus technical standards for a wide range of materials, products, systems, and services. ASTM standards on medical device and implant (These apparatuses are used in surgical procedures that involve the placement of such devices to specified parts and structures of the body (both humans and animals) for the purpose of enhancement or as an aid in a disability) are instrumental in specifying and evaluating the design and performance requirements of a number of biomedical materials, tools, and equipments.

Authorized Representation: The India Authorized agent/representative is a person/company that granted Power of Attorney by the foreign manufacturer who wants to register/Sale their medical device in India. Foreign manufacturers of medical devices who want approval and distribute their medical device (regulated devices) in India must appoint an Indian Authorized Agent. Also called as importer-trader.

Baseline Studies: The purpose of a baseline study is to provide an information base against which to monitor and assess an activity's progress and effectiveness during implementation and after the activity is completed. In MvPI, it helps to understand manufactures compliance with global regulators action/advice.

BIS: The Bureau of Indian Standards is the National standards body of India working under the aegis of Ministry of Consumer Affairs, Food & Public Distribution, Government of India. They represent medical devices in ISO and formulate Medical device standards in India.

CDSCO: The Central Drugs Standard Control Organization is the National regulatory body for Indian pharmaceuticals and medical devices, and serves parallel function to the European Medicines Agency (CE Marking) and US FDA.

Clinical Establishment Act: The Clinical Establishments (Registration and Regulation) Act, 2010 has been enacted by the Central Government to provide for registration and regulation of all clinical. Establishments in the country with a view to prescribe the minimum standards of facilities and services provided by them.

Corrective Action and Preventive Action: Corrective and preventive action (CAPA, also called corrective action / preventive action, or simply corrective action) are improvements to an organization's processes taken to eliminate causes of non-conformities or other undesirable situations.

Distributor: A medical device distributor can be an authorized representative of medical device manufacturer who has no direct presence in India or representative of a legally registered manufacturer in India.

Intended purpose: The use for which the device is intended according to the data supplied by the manufacturer on the labeling, in the instructions for use/user manual and/or in promotional materials

ISO: ISO is an independent, non-governmental international organization with a membership of 162 national standards bodies who creates standards for products but not limited to medical device.

IVD: A medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles.

Malfunction or deterioration: Failure of a device to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions.

Manufacturer: For the purpose of this document, the term "manufacturer" must be understood to include the manufacturer, its authorized representative or any other person who is responsible for placing the device in the Indian market.

MDAE: Medical device adverse event means patients/consumers, healthcare professionals and manufacturer who found an unanticipated event or incident related to a medical device.

Medical Device Alerts: Medical devices Alerts (MDA's) are the prime means of communicating safety information to clinical establishments on medical devices.

Near Miss Event: A Near miss event is an unplanned event that did not result in injury, illness, or damage – but had the potential to do so.

Post Market Surveillance: Post marketing surveillance (PMS) (also post market surveillance) is the practice of monitoring the safety of a medical device after it has been released on the market.

Recall: A product recall is a request to return a product after the discovery of safety issues or product defects that might endanger the consumer or put the maker/seller at risk of legal action. Root Cause Analysis: It is a method of problem solving used for identifying the root

causes of faults or problems.

Serious public health threat : Any event type which poses an imminent or potential threat to life, or may result in death, serious injury and/or illness that requires prompt remedial action.

Seriousness of event: (also known as serious deterioration in state of health) is either a life-threatening illness or injury, permanent impairment of a body function, cause congenital abnormality or permanent damage to a body structure -- a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.

Service-life or shelf-life: The time for which a device is intended to remain functional after it is manufactured, put to use, and maintained as specified.

Signal Detection : Signal detection means identifying patterns of adverse events associated with a particular medical device that warrant further investigation.

Suo motu Analysis: Suo motu, meaning "on its own motion," is a Latin legal term, approximately equivalent to the term sua sponte. For example, it is used where a government agency acts on its own cognizance.

Unanticipated death or unanticipated serious injury: A death or serious injury is considered unanticipated if the condition leading to the event was not considered in a risk analysis performed during the design and development phase of the device. There must be documented evidence in the design file that such analysis was used to reduce the risk to an acceptable level.

Annexure 1

Collaborating with MvPI: List of Hospitals & Technical support centre

1. Department of Pharmacology & Biomedical Engineering, Postgraduate Institute of Medical Education and Research, Chandigarh
2. Department of Biomedical Engineering, Christian Medical College , Vellore
3. Department of Pharmacology, All India Institute of Medical Sciences, New Delhi
4. Healthcare Technology, National Health System Resource Centre, New Delhi
5. Biomedical Technology Wing, Sree Chitra Tirunal Institute for Medical Sciences & Technology, Kerala
6. Andhra Medtech Zone Ltd., Andhra Pradesh
7. Department of Biomedical Engineering, Glocal Group of Hospitals, Kolkata
8. Department of Pharmacology & Biomedical Engineering, Dayanand Medical College and Hospital, Ludhiana
9. Department of Biomedical Engineering, Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry
10. Department of Biomedical Engineering, Narayana Health, Karnataka
11. Department of Biomedical Engineering, Sanjay Gandhi Post Graduate Institute of Medical College, Lucknow
12. Department of Biomedical Engineering, National Institute of Mental Health & Neuro Sciences, Bengaluru
13. Department of Clinical Pharmacology, Mysore Medical College and Research Institute, Karnataka
14. Department of Pharmacy practice & Biomedical engineering, Sri Ramakrishna Hospital, Coimbatore, Tamilnadu

15. Department of Quality Systems, Royal Care Hospital, Tamilnadu
16. Dept. of Pharmacology, Saheed Laxman Nayak Medical College and Hospital, Khoraput
17. Department of Pharmacology, Konaseema Institute Of Medical Science Amlapuram, Andhra Pradesh
18. Department of Oral and Maxillofacial Surgery, Maratha Mandal's Nathajirao G Halgekar institute of Dental Sciences & Research centre Belagavi
19. Department of Pharmacology, All India Institute of Medical Sciences, Bhopal
20. Quality cell, Yashoda Super Speciality Hospital, Ghaziabad, Uttar Pradesh
21. Department of Pharmacology, Veer Surendra Sai Institute of Medical Sciences and Research , Odisha
22. Biomedical Wing, District Hospital Mavelikkara, Kerala
23. Department of Pharmacology, Hamdard Institute of Medical Sciences & Research Jamia Hamdard, New Delhi
24. Department of Pharmacology & Biomedical Engineering , Frontier Lifeline Hospital Pvt Ltd, Chennai, Tamilnadu
25. Department of Pharmacology, Lady Hardinge Medical College, New Delhi
26. Department of Pharmacology, Dr Sampurnanand Medical College, Rajasthan
27. Department of Pharmacology, All India Institute of Medical Science, Patna
28. Department of Pharmacy Practice, St. James College of Pharmaceutical Sciences, Kerala
29. Department of Clinical and Experimental Pharmacology, School of Tropical Medicine, Kolkata
30. Department of Pharmacy, Jagadguru Sri Shivarathreeshwara College of Pharmacy, Ooty

31. Department of Pharmacology, All India Institute of Medical Sciences, Rishikesh
32. Department of Pharmacology, Hassan Institute of Medical Sciences, Karnataka
33. Department of Pharmacy, Parul Institute of Pharmacy, Gujarat
34. Department of Pharmacology, Dr. Pinnamaneni Siddhartha Institute of Medical Sciences & Research Foundation
35. Department of clinical Pharmacology, Tata Centre for Treatments, Research and Education In Cancer, TMH Mumbai
36. Department of Pharmacology, Kempegowoa Institute of Medical Sciences, Banglore
37. Department of Pharmacology, Govt. Medical College Shivpuri, Madhya Pradesh
38. Department of Pharmacology, All India Institute of Medical Sciences, Bhubaneshwar
39. Department of Pharmacology, NRI Medical College and General Hospital, Andhra Pradesh

*For updated MDMC list, kindly visit IPC website - www.ipc.gov.in.

Collaborating with MvPI: List of Medical device Industry Association

1. AIMED
2. CII
3. FICCI
4. PHD chamber of commerce
5. AMCHAM