



# TATA ELXSI

GLOBAL REGULATORY REQUIREMENTS AND  
MANUFACTURERS RESPONSIBILITIES FOR MEDICAL  
DEVICE VIGILANCE REPORTING

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## ABSTRACT

Globally, every country has its mandatory regulatory requirements that need to be fulfilled for legally marketing medical device in the region. To sustain medical devices in the regulated and semi-regulated markets, manufacturers need to ensure that post-market surveillance machinery is an integral component of the manufacturer's quality management system. It is critically important that the safety and performance of medical devices are continually assessed by the manufacturers to ensure patient/user safety. Manufacturers track and investigate the reported incidents, and ensure dissemination of information to relevant stakeholders. Hence, it is important for the businesses to be aware and understand the vigilance reporting requirements of all the authorities that they operate under. The purpose of this paper is to understand the global regulatory requirements and manufacturers' responsibility towards the medical device vigilance system.



## INTRODUCTION

Medical devices are regulated differently across the globe and each country, be it regulated or semi-regulated market, has its mandatory requirements for medical device classification, product launch, and post-market surveillance of devices.

To date, the majority of medical devices have not undergone pre-market preclinical and clinical studies. Moreover, the design changes and modifications over time are not subject to human trials. Therefore, there is a need for strong post-market surveillance data to ensure safety and performance of medical devices in the field and also ensure reduced probability of reoccurrence of incidents associated with the use of a medical device.

Robust, well-documented complaint/incident reporting processes need to be in place not only to meet the regulatory requirements, but also to provide evidence to manufacturers that their medical device continues to operate as designed, is performing as expected, and remains state-of-the-art.

Manufacturers are required to develop a tool/database to register the complaint, perform the product complaint investigation, and assess reportability to the regulatory agency. Some of the regulatory agencies such as The United States Food and Drug Administration (US FDA) require incident reporting through electronic format while some allow both paper & electronic formats. Most of the authorities make this information publically available through databases such as Manufacturer and User Facility Device Experience or MAUDE, Database of Adverse Event Notifications or DAEN, and others.

In addition, trend report are required to be submitted to the regulatory agency if any statistically significant increase in the frequency or severity of incidents are expected. For example, all medical devices carry a certain level of risk in their clinical use and may suffer from mechanical, electrical, or biological failures. Other incidents such as physical damage, incorrect use, or malfunction may also result in death or serious deterioration in the health of patients/users. Outcomes of these incidents could range from undesirable side-effects, non-serious incidents that could impact the benefit-risk to serious incidents. Hence, manufacturer/importer must track and report such incidents to the national regulatory agency in the region, where the incident occurred, and critical information must be shared in other regions where the same device is marketed. Furthermore, medical device safety communications such as field safety corrective actions or FSCAs are required to be circulated to the affected users with a copy to national regulatory agency in the form of Field Safety Notice or FSN.

The purpose of this white paper is to understand the global regulatory requirements and manufacturers' responsibility towards the medical device vigilance system. This vigilance system helps to improve the protection of health and safety of patients, healthcare professionals, and other users by reducing the likelihood of reoccurrence of incidents related to the use of a medical device.

## HISTORY

Since 1965, the Canada Vigilance Program collected and assessed the reports of suspected adverse reactions to health products, including medical devices, which can be accessed through the Canada Vigilance Adverse Reaction Online Database.

The post-market surveillance of medical devices was initiated in the United States of America with the passing of the Food and Drug Administration Modernization Act 1970. The Section 522 of the Food and Drug Modernization Act (FDAMA) made mandatory for the manufacturers to conduct PMS of any device which is either a class II or class III device.

In 1989, the Therapeutic Goods Act in Australia provided standardized national controls over goods used in the prevention, diagnosis, treatment, or mitigation of a disease, disorder, defect, or injury.

The National Health Surveillance Agency (ANVISA), Brazil's national regulatory agency, conducts vigilance and market surveillance activities in several areas such as drugs, food, cosmetics, and medical devices.

To accomplish uniformity and harmonization across the national medical device regulatory systems and to boost the access to safe, effective, and clinically beneficial medical technologies, the Global Harmonization Task Force (GHTF) was formed in 1992 by five members: European Union, United States, Australia, Japan, and Canada wherein the device vigilance was among the study groups.

In June 1993, the vigilance requirement for medical devices was published as Council Directive 90/385/EEC and 93/42/EEC, followed by incorporation of amendments of MEDDEV guidance 2.12–1 revision 8 in January 2013 by the European Union.

The recent high-profile incidents such as the hip replacements and the breast implant crisis highlighted the urgent need for regulatory reform, and improvement in standards, processes, and procedures. In May 2017, the EU parliament approved and released the new regulations Medical Device Regulation (EU MDR 2017/745) and the In-Vitro Diagnostic Device Regulation (IVDR 2017/746) that laid out structured requirements for post-market surveillance.

The China medical device adverse event monitoring network and reporting system began in 2010. The National Medical Products Administration (formerly known as China Food and Drug Administration or CFDA) is the body responsible for the medical devices' legislation and its implementation, including post-market surveillance and vigilance.

## PURPOSE OF THE VIGILANCE SYSTEM

A vigilance system is required to improve the patient/user safety, by reducing the repetition of similar types of incidents or by decreasing the consequences of such incidents. This can be achieved by the tracking and investigation of reported incidents, and the dissemination of information. Following are key objectives of a streamlined and compliant vigilance system:

- To help regulatory authorities in monitoring manufacturers' follow-up towards reported incidents.
- To facilitate early and direct implementation of field safety corrective action, by easy correlation of data between regulatory authorities and manufacturers.
- To monitor the incidents/experience with similar devices produced by different manufacturers.
- To provide vigilance aids in identifying new or escalating risks with a device, as well as feasible improvements to the usability or functionality of the device.
- To report device failures to manufacturers or regulators and help in identifying risks at the earliest possible time point.



## REGULATORY REQUIREMENTS OF MAJOR MARKETS

Medical Device incident reporting is one of the post-market surveillance tools the regulatory agency uses to monitor device safety and performance, identify potential device-related safety issues, and finally contribute to benefit-risk assessments of the products. Mandatory reporters (i.e., manufacturers, importers, and device user facilities) are required to submit the adverse events and device-related incidences to the regulatory agencies within a specified time. Besides, the regulatory authorities also encourage health care professionals, patients, caregivers, and users to voluntarily submit serious adverse events associated with a medical device, use errors, product quality issues, and therapeutic failures. These safety reports, along with data from other sources, can provide critical information to manufacturers/regulatory agency which helps to improve patient safety.

The GHTF established the requirements for post-market surveillance that cover after-sale obligations, device performance monitoring, problem identification, adverse events reporting, safety alert, recall, and corrective actions.



| COUNTRY                             | EUROPE (MDR)  | USA   | JAPAN   | CANADA   | AUSTRALIA   | BRAZIL   |
|-------------------------------------|---|---|---|--|---|--|
| <b>Regulatory Agency/ Authority</b> | The Competent Authority of the Member State in which that incident occurred | The Food and Drug Administration (FDA)  | Ministry of Health, Labour and Welfare/ Pharmaceuticals and Medical Devices Agency  | Health Canada  | Therapeutic Goods Association (TGA)   | Agência Nacional de Vigilância Sanitária (ANVISA)  |
| <b>What to report and when</b>      | ‘Serious Public Health Threats’ no later than 2 days of becoming aware      | Serious Public Health Threats should be submitted within 5 days of becoming aware of an event | MAH should report the matters specified in the items of Article 228-20, Paragraph 2 of the Enforcement Regulations          | Serious deterioration in health also includes a serious public health threat         | ‘Serious Threat to Public Health’ no later than 2 days after becoming aware | Death’, ‘Serious Public Health Threats’ and ‘Counterfeit Devices’ no later than 3 days (72 hours) after becoming aware         |
|                                     | ‘Serious Incidents’ no later than 10 days of becoming aware                 | Deaths, serious injuries and malfunctions should be submitted within 30 day of becoming aware | Death & other serious events (Within 15 calendar days)  | A mandatory serious incident should be submitted within 10 days of becoming aware    | ‘Adverse Events’ no later than 10 days after becoming aware                 | Adverse Events’, whose recurrence has the potential to cause a major adverse event’ no later than 10 days after becoming aware |
|                                     | ‘Incidents’ no later than 15 days of becoming aware                         |   | The same cases as described above that could be attributed to the malfunction of the medical device within 30 calendar days | A mandatory non-serious incidents should be submitted within 30 days of coming aware | ‘Near Adverse Event’ no later than 30 days after becoming aware             | Technical Complaints, which may lead to a major adverse event,- no later than 30 days after becoming aware                     |

| COUNTRY                                     | EUROPE (MDR)   | USA  | JAPAN   | CANADA   | AUSTRALIA  | BRAZIL  |
|---|--|--|---|--|--|---|
| <b>Trend or Periodic Reporting required</b> | Yes – Trend Reporting (Article 88) and PSUR (Article 87) | Alternative Summary Report (ASR).  | Periodic Reporting  | No   | Periodic safety reports (PSR) & trend report       | Annual reports are submitted for the first 3 years of device approval |
| <b>How to report</b>                        | Via EUDAMED*   | 1. Electronically submit Medical Device Reports: 2. Web interface using the eSubmitter application AS2 Gateway-to Gateway using HL7 ICSR XML | To consult by telephone with PMDA and upload to the designated website page of PMDA | Via email, fax (613-954-0941) or mail: Canada Vigilance – Medical Device Problem Reporting Program | Via IRIS   | Via SNVS  |
| <b>Information publicly available</b>       | Via EUDAMED*   | Via Manufacturer and User Facility Device Experience (MAUDE)   | Available only in their local language  | -  | Via Database of Adverse Event Notifications (DAEN) | Available only in their local language                                |

\*At the time of publication of this White Paper, the EUDAMED Database is under construction



## European Union

The EU MDR and EU IVDR will fully apply in the EU Member States from May 26, 2021, and May 2022 respectively. The new regulations strengthen vigilance, post-market surveillance, and other requirements for manufacturers.

The European Commission's Guidelines document on a medical device's vigilance system (MEDDEV 2.12 -1 rev. 8 January 2013) illustrates that manufacturers are required to notify the relevant national competent authority about incidents and field safety corrective actions (section 5.1 and 5.4 of MEDDEV 2.12 -1 rev. 8). The manufacturer is also required to investigate/evaluate the incidents and take necessary corrective action (section 5.2 and 5.3 of MEDDEV 2.12 -1 rev. 8).

## United States

The Medical Device Reporting regulation (21 CFR Part 803) contains mandatory requirements for manufacturers, importers, and device user facilities to report certain device-related adverse events and product problems to the FDA.

On Feb. 14, 2014, the FDA published a rule, stating manufacturers and importers are required to submit initial and supplemental adverse event reports in electronic format through FDA's Electronic Submission Gateway (ESG).

The MAUDE database holds medical device reports submitted to the FDA by mandatory/voluntary reporters and available online to the public.

## Australia

The Therapeutic Goods Administration or TGA's official webpage has a "safety information" section, which provides information on current and historic recalls of medicines and medical devices, advice issued by TGA about products, monitoring communications, information on reporting problems, and how the safety of the therapeutic product is monitored.

In 2012, the DAEN, was launched to support better health outcomes by providing access to the information that the TGA gathers while monitoring medical devices' safety in Australia.

TGA's Incident Reporting and Investigation Scheme (IRIS) emphasizes adverse events/incidents related to the use of medical devices. The investigations of incidents or potential adverse events reported from devices' users can lead to actions such as product recalls, safety alerts, product improvement, user education, and compliance testing.

## China

The National Medical Products Administration or NMPA (formerly known as China Food and Drug Administration or CFDA) established in 1998 and structured around two main departments dealing with medical devices:

- Department of Registration
- Department of Supervision

Medical device manufacturers, importers, distributors, and medical institutions are responsible for filing a report on suspicious medical device adverse event (AE) with their local medical device monitoring institution and the legal agent.

According to the decree, NMPA adverse events reporting timelines are:

- Suspected medical device-related death shall be reported within 7 days
- Serious Adverse Events (SAEs) within 20 days;
- Overseas Adverse Events 30 days
- Public Health Hazard shall be reported in 12 hours

Serious AEs outside of China must be reported to the NMPA within 15 working days. Within 20 working days of the initial report, the medical device manufacturer must also file a “Supplementary Report on Medical Device Adverse Event,” providing more details about the adverse event. Additionally, manufacturers of Class II and III medical devices must file an “Annual Report on Medical Device Adverse Events” with their local monitoring institution each year by the end of January, summarizing and analyzing the AEs over the past year.

### **Eurasian Economic Union (EEU)**

The Eurasian Economic Union entered into force on 1 January 2012 and includes the Republic of Armenia, the Republic of Belarus, the Republic of Kazakhstan, and the Russian Federation.

In March 2017, the Belorussian Ministry of Health clarified its requirements for reporting adverse events for manufacturers of medical devices. All the serious or unexpected adverse events during its usage/exploitation, peculiarities of interaction with other medical devices must be reported to the regulatory agency.

The Government of the Russian Federation's Order No. 323 dated 30 June 2004 “On the approval of the statement on the Federal Service for Surveillance in Healthcare”, state functions related to the safety monitoring of medical devices are assigned to the Federal Service for Surveillance in Healthcare (Roszdravnadzor). Any information related to adverse events in Russia shall be submitted to Roszdravnadzor. Any adverse event that poses a serious threat to the public is to be submitted immediately after the causality assessment, but no later than 2 days after being made aware. Death or other serious incidents to be submitted immediately after causality assessment, but no later than 10 days. All other adverse events, for which there is no need for immediate reporting, is to be submitted soon after causality assessment, but no later than 20 days.

## **Singapore**

National regulatory authority of Singapore i.e., Health Sciences Authority or HSA, as part of its vigilance post-market surveillance activity, runs a system for the collection and distribution of FSCA, to ensure the safety of medical devices suspected of being potentially harmful to users, due to nonconformity to quality, safety, and performance requirements.

The adverse event reporting timelines are:

- Within 48 hours for events that represent a serious threat to public health;
- Within 10 days for events that have led to the death, or a serious deterioration in the state of health, of a patient, a user of the medical device, or any other person;
- Within 30 days for events where a recurrence/repetition of which might lead to the death, or serious deterioration in the state of health, of a patient, a user of the medical device or any other person

All information regarding medical devices registered in Singapore are made publicly available online through the Singapore Medical Device Register (SMDR) database.

## **Argentina**

National Administration of Drugs, Foods, and Medical Devices (ANMAT) is the medical device regulatory authority of Argentina and is responsible for the authorization, registration, standardization, and vigilance and monitoring of devices with the specific purpose of ensuring their compliance with efficacy, safety, and quality requirements.

Techno-vigilance program was developed by ANMAT to collect, access, and manage medical devices' adverse events and this program helps the early detection of adverse and performance failure in the stage of widespread use.

## **Mexico**

In Mexico, the Federal Commission for the Protection against Sanitary Risks (COFEPRIS) is responsible for ensuring high quality, effectiveness, and safety of the medical devices. In early 2013, the techno vigilance system was introduced to support post-market device monitoring and management of adverse event reporting and corrective actions. The COFEPRIS website provides information only in Spanish.

## MANUFACTURERS RESPONSIBILITY

Manufacturers are responsible for reporting all serious incidents immediately after analyzing the causal relationship between the incident and device, and circulate FSNs to the relevant competent authorities.

After serious incident notification, the manufacturers are necessary to implement a systematic procedure for incident investigations, to ensure that any risks or issues associated with the use of their device are identified at an early stage. If needed, an FSCA will be implemented to reduce the risk associated with the use of the device.

To ensure timely reporting of serious incidents, the manufacturer may submit an initial report that is incomplete and then follow up with the patients, doctors, or users to create a complete report. The well-defined process to perform the incident investigation, within a specified timeframe allows the final/follow-up conclusion to be submitted to the regulatory agency within the timeline. The final report will set out conclusions and, where relevant, indicate corrective actions to be taken.

### **Systematic approach to ensure timely submission:**

- Establish complaints receiving system, includes local telephone numbers, email addresses, fax, postal address, and other appropriate contact details of competent staff who can collate the required information
- Manufacturers/importers are required to maintain complaint files and establish and maintain procedures for receiving, reviewing, and evaluating complaints
- Manufacturers are required to develop a tool or database to register and process compliance
- Every complaint (written, electronic, or oral communication) must be evaluated /investigated to determine if it is a reportable adverse event
- Its manufactures/importers responsibility to assess the causal relationship between the device and the incident of:
  - The healthcare professional's opinion based on available evidence
  - The results of the manufacturer's respective preliminary assessment of the incident
  - Evidence of previous, similar Incidents
  - Other evidence held by the manufacturer
  - It's difficult to make a judgment when there are multiple devices and drugs involved.

- Criteria to assess the seriousness of the event:
  - The event which led, or might have led, to one of the following outcomes:
    - Death of a patient, user, or another people
  - Serious deterioration in state of health of a patient, user, or other person
    - life-threatening illness
    - permanent impairment of a body function or permanent damage to a body structure
    - a condition necessitating medical or surgical intervention to prevent life-threatening illness or permanent impairment
    - a condition that requires hospitalization or significant prolongation of existing hospitalization
    - any indirect harm (see definitions) as a consequence of an incorrect diagnostic or IVD test results when used within the manufacturer's instructions for use
    - fetal distress, fetal death, or any congenital abnormality or birth defects
- To establish complaint handling procedure i.e. receiving, processing, and regulatory submissions (via paper or electronic submission)

### Vigilance Workflow/Process Flow

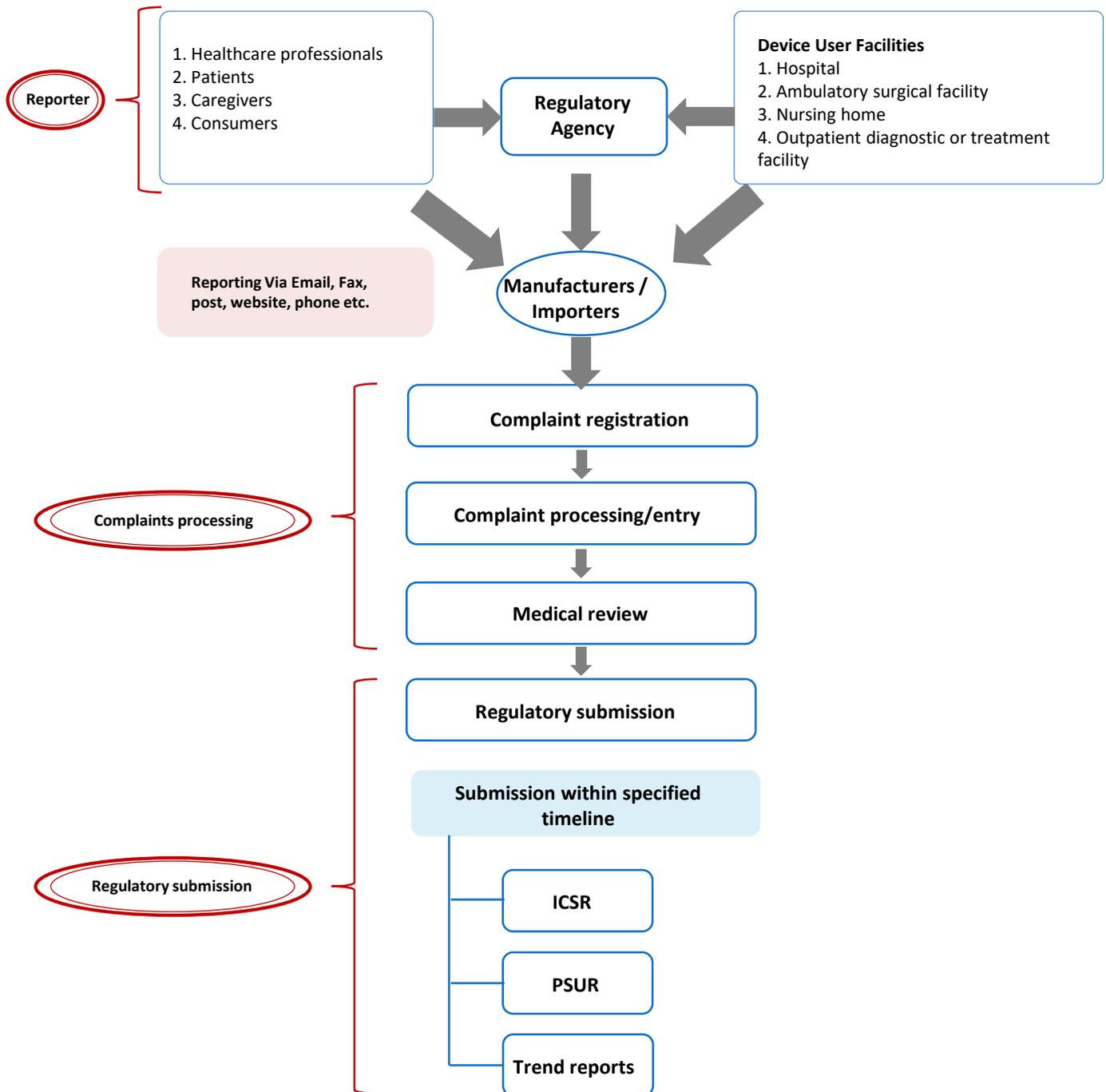


Figure: Vigilance process flow

### Complaint Handling Procedure

To support the reporting of vigilance, a complaint handling procedure should be established to facilitate the process. This may include:

- Definition of a complaint that requires to be broad enough to ensure compliance with vigilance requirements in all regions anywhere the device is placed on the market.
- Confirmation/clarification on how the first time awareness date of the complaint is established to allow a deadline for vigilance reporting.

- Mandate to report complaints within a set period to allow on-time vigilance reporting.
- Manufacturer Incident Report (MIR) form to capture all the required information to the database and investigate the incident.
- Process for obtaining the complaint product(s) back, or images from a procedure to allow for a thorough investigation to be completed and a root cause established wherever possible.
- Trending process to understand the escalation of any product issues, which further helps in planning the action where required (e.g. a recall, FSCA).

Manufacturers will submit a trend report to the regulatory agency if any statistically significant increase in the frequency or severity of incidents is expected, for example, undesirable side-effects or non-serious incidents that could have an impact on the benefit-risk analysis. Such incidents may lead to risks to the health or safety of patients, users, or other persons that are unacceptable when weighed against the intended benefits.

### **Dissemination of Information**

A key part of the medical device vigilance system is the dissemination of information, which helps to prevent the recurrence of incidents or to alleviate the consequences of such incidents.

When the competent authority notifies a manufacturer to communicate the suspected serious incident reported by a healthcare professional, patient, or user, the manufacturer is required to

- Submit a serious incident report to the respective competent authority within the timeframe.
- Submit an explanatory statement, to the competent authority, if the manufacturer believes the suspected serious incident does not fulfill the reporting criteria.

Medical device safety communications need to be circulated to healthcare professionals and medical device 'users'. Those are:

- Communications circulated by the manufacturer or their local agent - field safety notice (FSN).
- Communications circulated by a regulatory agency.

Manufacturers will ensure that the FSCA related information is brought to the attention of users of the device under question utilizing an FSN without having any delay. Examples of some actions that can be communicated via an FSN include:

- Medical device recall
- Device modification or design change
- Device exchange
- Device destruction

Some guidelines state how FSN can be written and circulated. The manufacturer can send the FSN by either email, post, fax, or in some instances, hand-deliver the notice.

The FSN includes the correct identification of the manufacturer (by including, if issued, SRN), the device or devices affected (by including the relevant UDIs), and clear explanation, without understating the level of risk and reasons for the FSCA.

## CONCLUSION

Manufacturers/importers need to be aware and understand the vigilance reporting requirements of all the authorities that they are operating under. Robust, well-documented complaint/incident reporting processes need to be in place not only to meet the regulatory requirements, but also to provide evidence to manufacturers that their medical device continues to operate as designed, is performing as expected, and remains state-of-the-art. Manufacturers are required to develop a tool/database to register the complaint, perform the product complaint investigation, and assess reportability to the regulatory agency. Some of the regulatory agencies require incident reporting through electronic format (for example, US FDA) and some allow both paper & electronic format. Most of the authorities make this information publicly available through the database (for example, MAUDE, DAEN, etc.). The medical device vigilance system is required to improve the protection of the health and safety of patients and users by reducing the probability of reoccurrence of incidents associated with the use of a medical device. The trend report needs to be submitted to the regulatory agency if any statistically significant increase in the frequency or severity of incidents. Medical device safety communications, for example, FSCAs are required to be circulated to healthcare professionals and users without delay by the means of FSNs.

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# TATA ELXSI

## ABOUT TATA ELXSI

Tata Elxsi, a part of Tata Group, is amongst the world's leading providers of design, engineering, and regulatory compliance services. With 15+ years of experience in catering to medical device and healthcare companies, Tata Elxsi has built a strong services and solutions portfolio that adds value at every stage of the customer's product development lifecycle.

Apart from product engineering, Tata Elxsi has 1000+ person-years of experience in providing regulatory compliance services such as consulting, technical file remediation, compliance testing, clinical evaluation, post-market surveillance, packaging, and labeling services.

For more information, please visit [www.tataelxsi.com](http://www.tataelxsi.com) click here 

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