ABSTRACT
Medical device vigilance is concerned about device problems (incidents) their analysis and mitigation to ensure that device performance is good and that patient safety are maintained. The main aim of this is to outline the criteria of the medical device vigilance program and to highlight the requirements that still remain in the state laws of regulated markets (US & EU) and to increase access to safe, reliable and therapeutic benefits. The severity of the Subject, risk assessment should carried out by the manufacturer prior to marketing. In US, Medical Device surveillance deals with post-marketing monitoring where the manufacturer or importer is required submit reports to regulatory authorities; same as in the EU. US medical device tracking system involved with different sections to update adverse event. The user or manufacturer has to report incidents to member states where necessary actions are to be taken as early as possible to protect or reduce hazard of casualty or severe decline in terms of safety and quality by implementing the CAPA for risk analysis.

Keywords: Vigilance, FSCA, PMS, Medical device, FTA, US, EU.

INTRODUCTION
Under the post market surveillance of medical device in US, passed a legislation of FDA Modernization Act 1970 for Class II & III devices. Council directive of 90/385/EEC & 93/42/EEC published for manufacturer and member states to support the vigilance requirements of medical device, and MEDDEV guidance to attain equivalence between access to safe and effective.

OBJECTIVES
• To minimize potential risk of use, ensure that the intended consumer is capable od using medical device safely and efficiently throughout the product life cycle.
• To identify potential design-related risks in both normal and liability circumstances
• To evaluate hazards of medical device by risk analysis and its control measures.

DISCUSSION
Assessment of precise risks can be determined by two methods:
• Fault tree analysis (FTA) (Figure 1)
• Failure mode and effects analysis

The logic gates determines whether the sub event probabilities or frequencies should be multiplied, for an AND gate or an OR gate.
And gate – if all events under a gate are necessary for the higher event to occur, an AND gate is used.
Or gate – if each of the event sufficient to produce the higher event on its own, an OR gate is used.

Figure 1: Fault tree analysis process
Where in case of EUROPE the risk analysis is carried out on,
• Identifying the hazard(s)
• Identifying the subject(s) at risk
• Describing the potential harm
• Describing how the hazard may harm the subject; hence the risk analysis between US And EU follow same procedures

UNITED STATES OF AMERICA (USA)
The US legal regulatory basis is based on statutes enacted by the US Congress and federal regulations, which determine how statutes are implemented by federal agencies such as the FDA. Requirements for reporting adverse events for marketed medical devices are provided by the Medical Devices Regulations (21 CFR Part 803).

Guidance documents issued by the FDA are not enforceable as law but provide guidance documents for the FDA’s interpretation of the regulations. Relevant FDA guidance documents regarding adverse event reporting include the following:
• Medical Device Reporting: An Overview (April 1996);
• Medical Device Reporting for User Facilities (April 1996)
• Medical Device Reporting for Manufacturers (March 1997).

Submitting to eMDR
The FDA has two options for manufacturers and importers to electronically submit MDRs:
• Web Interface using the eSubmitter application
• AS2 Gateway-to-Gateway using HL7 ICSR XML.

EUROPE
EU Pharmacovigilance System: Legal and Regulatory Basis
The legal base and regulatory guidance concerning adverse event reporting within the system and the reporting of adverse events experienced in the clinical assessment of medical devices are found in the following legal acts and documents:
• Medical Devices Directive (Directive 93/42/EEC)
• In Vitro Diagnostic (IVD) Medical Devices Directive (Directive 98/79/EC)
• Active Implantable Medical Devices (AIMD) Directive (Directive 90/385/EEC)

Hazard Handles Measure
Defending actions, e.g. default in use modes
Information for safety, e.g., warnings in labeling
Many actions have need of interference:
• Right reaction for the conditions, e.g. a patient-specific response
• Timeliness

The severity and possibilities of harm can be reduced by risk reduction measures. Risk control strategy also includes the process that advance to detect ability of hazardous and quality risks.

Safety Risks Zones
Vigilance system for medical device aims to promote the immediate, early, and harmonized application of FSCA in all Member States where the device is in use, opposed to the country by country action (Figure 2).

MEDICAL DEVICE TRACKING
Follow-up of the device should be carried out to know the results of the user and patients to assist manufacturer to reduce adverse effects or recall if any major deficiency is found in the device.

Tracking System
US- Post-market surveillance
EMA- adverse incident tracking system (AITS)

Criterion for an Event to be Reported to Competent Authorities by Manufactures
• An occurred incident.
• Incident of medical device
• Death of a patient.

Vigilance Exchange Program
Intend to exchange information are:
• Confidential information
• Non-confidential information.

Serious incidents related to device and its global distribution would influence exchange between NCAR.

Basis:
1. Consequential
2. Rpidity of the occurrence
3. Populace that is susceptible (newborn or aged)
4. Avertable
5. Community fear or offend. e.g.; lead aprons containing radioactive material
Table 1: Time scales to issue a FSCA:

<table>
<thead>
<tr>
<th>Draft notification of safety in the field</th>
<th>Comment for minimum of 48 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reply to EU on FSCA queries</td>
<td>Written declaration in the event of a critical government risk or 21 days.</td>
</tr>
</tbody>
</table>

Table 2: Mandatory Reporting Requirements for Manufacturers and Importers: (US)

<table>
<thead>
<tr>
<th>Reporter</th>
<th>What to report</th>
<th>Report form</th>
<th>To whom</th>
<th>When</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>Deaths, severe injuries, and malfunctions reported for 30 days</td>
<td>3500A Form FDA</td>
<td>FDA</td>
<td>Awareness of an case within 30 calendar days</td>
</tr>
<tr>
<td></td>
<td>5-day report for a case designated by FDA or an incident requiring remedial action to avoid excessive risk of serious public health damage</td>
<td>3500A Form FDA</td>
<td>FDA</td>
<td>Awareness of case within 5 working days.</td>
</tr>
<tr>
<td>Importers</td>
<td>Death and severe injuries reports</td>
<td>3500A Form FDA</td>
<td>FDA</td>
<td>Awareness of a case within 30 calendar days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3500A Form FDA</td>
<td>Manufacture and FDA</td>
<td>Awareness of a case within 30 calendar days</td>
</tr>
</tbody>
</table>

Table 3: Comparison between US and EU

<table>
<thead>
<tr>
<th>Parameters</th>
<th>US</th>
<th>EU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post marketing monitoring activities</td>
<td>Tracking of medical device, MDR Event files, documents and written processes, handling of complaints.</td>
<td>Adverse events reporting FSCA and safety reports, inquires, clinical follow-up documents post-market enforcement.</td>
</tr>
<tr>
<td>Types of reports</td>
<td>30–day reports, 5-day reports, baseline reports, additional reports, annual reports.</td>
<td>Periodic reporting of trends, Initial reporting of adverse events, final reports.</td>
</tr>
<tr>
<td>Exchange of surveillance</td>
<td>For all products regulated under US and EC Law as a medical device, post-market vigilance reports will be exchanged</td>
<td>Exchange data in and out of FSCA and comparable events.</td>
</tr>
<tr>
<td>Follow-up of medical device</td>
<td>Have a monitoring system been in place since 1993</td>
<td>AITS created by evaluating user accounts to explore the device failures modes.</td>
</tr>
<tr>
<td>Analysis of danger</td>
<td>Analysis of the faulty tree.</td>
<td>By defining the topic of danger, severity.</td>
</tr>
<tr>
<td>Time to report</td>
<td>Within thirty business days</td>
<td>There are usually 10 working days for European manufactures to submit initial reports.</td>
</tr>
<tr>
<td></td>
<td>Within five business days</td>
<td>There are 30 calendar days for severe injuries and near incidents.</td>
</tr>
<tr>
<td>Not incidents reportable</td>
<td>The supplier can send an RAE instance request: inaccurate information when the unit is produced by the other manufacturer</td>
<td>Client identified deficiencies, the root cause of the adverse event due to pre-existing conditions in patients, side effects obviously stated on the label of the manufacturer.</td>
</tr>
<tr>
<td>Records</td>
<td>Adverse events documents, assessment documents, monitoring and inspection documents</td>
<td>Adverse events documents, assessment documents, records compatible with consumer/user.</td>
</tr>
<tr>
<td>Recall</td>
<td>The manufacturer must trigger recall</td>
<td>The manufacturer must trigger recall.</td>
</tr>
<tr>
<td>Applicable forms</td>
<td>3500A-Form, 3500-Form, 3419-Form</td>
<td>Reporting of incidents and online incidents report.</td>
</tr>
</tbody>
</table>

6. Pros / risk ratio

Recall
Recall the FSCA to decrease the danger of damage to patients, operators or others or to minimize the re-occurrence of the occurrence. The following measures would be included in FSCA (Table 1):
- Return of a medical device to the manufacturer or its representative (which is termed recall)
- Device modification
- Device exchange
- Device destruction
- Advice given by manufacturer regarding the use of the device.  

Reporting Codes for Adverse Events
Med watch of medical device reporting handbook contains codes for adverse events which helps to fill FDA 3500A form.

User Facility Reporting Requirements
- Reports of death
- Reports of serious injury
• Send an annual report to FDA in Form3419 by January 1st of every year (Table 2 and 3).

**TYPES OF REPORT**

**Follow-up Report**

A follow-up report should be submitted by the manufacturer to NCA, when the investigation time is closer to the NCAs timelines in the original report.

**Final Report**

A report containing the results of the injury and its action in a statutory declaration

• Illustration of actions:
  • No action;
  • Extra device inspection in use.

**Trend Reports**

Trend reports must be presented when the rate of reportable events, incidents that are generally exempt from reporting, and events those are generally not reportable is significantly increased.

**CONCLUSION**

whichever technique is used, it is now compulsory during the design phase of a medical device, it is now mandatory to conduct a risk or danger analysis either by FTA( The most favored risk analysis method by the pacemaker manufacturer and FDA) or by the FEMA (plasma and blood virus inactivation systems)

Minimizing the process of human intervention would reduce risk and increase efficiency. The benefits of undertaking risk analysis during the construction of medical devices can be important and can be used to mitigate some or all of the cost of introducing risk of mitigation initiatives.

Thus manufacture need to be aware an understand vigilance reporting requirements of all of the jurisdictions that they operate under. Robust, well documented compliant an vigilance reporting process need to be in place not only to meet regulatory requirements, but also to provide evidence to manufacturers that their medical device continues to operate as designed, is performing as anticipated & remains state of the art.

**REFERENCES**

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