# Case Study – Post Market Product Monitoring System

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*SUMMARY*

Medical device manufacturers are responsible for ensuring that their medical products are safe, reliable and effective. In case of product deficiency, malfunction, or notification of patient harm; medical device manufacturers need to be able to track all devices and recall them if required. To have the ability to do this, they need to have a robust post market product monitoring system.

Food and Drug Administration (FDA), which is responsible for protecting the public health by assuring the safety and effectiveness of medical devices, requires medical device manufacturers to have a well defined post market surveillance program that includes post market surveillance studies as well as adverse event reporting.

This paper discusses all the elements of a robust post market surveillance program i.e. product monitoring system, using a practical example.

## *1 INTRODUCTION*

Post Market Surveillance (PMS) is the pro-active collection of information on safety, performance and quality, of medical devices, after their release into the market. Or in other words, it is the active, systematic, scientifically valid collection, analysis and interpretation of data on a product released into the market.

### *1.1 Background*

PMS requirements are authorized under section 522 of the Federal Food, Drug, and Cosmetic Act (FDCA). 21 C.F.R. Part 822 states that the FDA has the authority to order PMS of any Class II or III medical device that meets the following criteria:

- Failure of the device would be reasonably likely to have serious adverse consequences
- The device is intended to be implanted in the human body for more than one year or
- The device is intended to be used to support or sustain life outside a user facility

Several FDA recognized standards incorporate data from the post production phase in their recommended processes. For example, the international "ANSI/AAMI/ISO 14971:2007 Medical devices-Application of risk management to medical devices" standard mentions including post-production data to continuously update the risk management file [1]. This standard specifies a process for a medical device manufacturer to identify the hazards associated with medical devices, estimate and evaluate the associated risks, control these risks, and monitor the effectiveness of the controls during design and post-production phase. "ISO13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes" also mentions monitoring experience from the post-production phase and reporting adverse events [2].

### *1.2 Why is post market product monitoring system required?*

Every manufacturer would like to believe that their marketed product is manufactured under controlled condition, is used in accordance with product labeling and is safe and effective, since it was designed, tested and manufactured to meet all FDA recommended standards. However, in reality, products fail and people get injured. Rare adverse events may not be detected during testing and clinical trials due to limitations in sample size, variety of patient population recruited for the clinical trial, and test coverage under all foreseeable misuse and off label usage conditions. Also, prerelease testing is generally conducted with production equivalent test samples under very controlled conditions; hence the low frequency failure modes that occur under multiple fault scenarios may not be detected. Thus a robust post market monitoring system that continuously monitors and evaluates product performance and feeds the information back into the risk management process and to the engineering teams, is required to ensure that medical products are safe and effective throughout their lifecycle.

### *1.3 Benefits of post market product monitoring system*

There are several benefits to having a robust post market product monitoring system. A few examples of these benefits are

- An early warning for removal of suspect product from the market resulting in increased user and patient safety
- Reduced litigation
- Providing feedback to research and development (R&D) groups to improve existing products and designing new products
- More robust Quality Management System
- Greater regulatory standards compliance
- Enhanced quality image of the company resulting in increased revenue and profitability.

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## 2 POST-MARKET PRODUCT PERFORMANCE MONITORING

There are three essential phases in a medical product performance monitoring system.

| | |
|---|---|
| Phase1 | Gather Customer Experience |
| Phase2 | Product Evaluation and Investigation |
| Phase3 | Identify Trends via Statistical Analysis |

### 2.1 Phase1 : Gather Customer Experience

Customer Experience is the main input into the monitoring system. It includes any written, electronic, or oral communication that alleges a deficiency related to the identity, quality, durability, reliability, safety, effectiveness or performance of a medical product after it is released for distribution. Customer complaints, Corrective and Preventive Action (CAPA), recalls, post market clinical studies, field sales force, non conforming material/products and service records are some sources of customer experience data. A robust PMS system must establish a complaint system that funnels all complaint information from all the sources mentioned above into one central repository for processing. The complaint information should be reviewed, investigated, analyzed and trended on a regular basis. FDA and the ISO13485 requires at least an annual review meeting, but a robust PMS program should evaluate data more frequently (i.e. quarterly or monthly basis).

### 2.2 Phase 2 : Product Evaluation and Investigation

Reported customer product experiences and returned products must be investigated to ensure that all observations are completely documented and the root cause is understood. The investigation process may include consultation with field representatives and healthcare professionals to understand the clinical observation and to assess potential product involvement. The investigation may also include evaluation of supporting documentation and evidence such as X-rays, Electrocardiogram's (ECG), device programming, and information retrieved from device memory.

Laboratory analysis of returned product is a critical part of the investigation process. Many medical device companies have a separate Product Investigation Lab, where engineers and lab technicians perform detailed component level analysis on the returned product to determine the root cause of failure. In some cases, the components may be sent back to component manufacturers or third party independent labs for further analysis.

Manufacturing tests are sometimes repeated on the returned product to compare current results with tests done prior to shipping the product, to determine if current device behavior matches the original test performance. This information is useful during root cause investigation.

In this context, device traceability is the single most important step for the initiation of any investigation. Typically, control numbers are used to identify finished devices, components, and subassemblies during manufacturing and distribution so the history of the device can be determined by searching on control numbers in the data system. A control number can be any distinctive combination of letters or numbers. It is generally either:

- A serial number identifying a specific device or component, or
- A lot or batch number identifying a set of components or devices that have been purchased or produced under essentially the same conditions.

At the time of manufacturing, control numbers are recorded in the Device History Records and if possible on packages and/or package inserts or on the product itself. During product evaluation and investigation, the design history record (DHR) of a particular product is checked for pre-release information.

A comprehensive error coding system that captures the primary customer complaint, its related engineering investigation and cause for the failure, needs to be set up prior to launch, so data can be collected for risk analysis and trending or statistical analysis, as soon as the product is released. The service engineer or technician adds appropriate codes to adequately characterize the results of the evaluation of the customer complaint and any issues discovered during the service evaluation.

### 2.3 Identify Trends via Statistical Analysis

The product investigation details are used to identify trends and patterns in device behavior and process or component related issues. This is done by using Statistical Analysis techniques such as Data Mining, Reliability Modeling, Statistical Process Control, Text Analytics, and Predictive Modeling such as Regression, Forecasting etc. available in software packages such as SPSS, MINITAB and Weibull++.

Text Mining is a powerful tool that can convert unstructured free form text (e.g. description of customer complaints) into structured format and help correlate it with the root cause of failure.

If a pattern of similar product failures is identified, the investigation is expanded and a cross-functional team is assembled to determine whether a pattern exists, followed by further investigation of the pattern to determine root cause.

## 3 CASE STUDY

This case study is divided into two main sections. The first section covers background information on effective post market data management process and the second section covers an example on evaluating a post-market product quality issue.

### 3.1 SAP Data Management

Custom designed modules in SAP (which stands for “Systems, Applications and Products in Data Processing”), form the backbone of the product monitoring system at the medical device manufacturer’s facility. A brief description of the custom designed modules is given below:

- Incoming Material Module- This is used by incoming

inspectors to track the materials and their associated lot numbers from the suppliers.

- The electronic Design History Record (eDHR) Module – This is used on the production floor, and it houses the information on every subcomponent and every test run on each product manufactured. In the medical device industry, the manufacturer is responsible for maintaining traceability of their Class II and Class III devices. In case of product deficiency, malfunction, or notification of patient harm; medical device manufacturers need to be able to track all devices and recall them if required. To have the ability to do this, they need to know what components went into each product, who the product was sold to and when it was sold. In case of a recall, they need to be able to contact each customer, who bought the affected product, and ask them to return it. The eDHR system helps to maintain this traceability. Every sub-component is scanned while it is being manufactured and assembled into the final product and results of every test performed on the production floor are saved in eDHR record.
- The Sales Module – This is used by the sales team and it houses all the customer information (e.g. purchase order number, customer contact information, shipping address, date of purchase, warranty information, type of product model etc).
- The Customer Support Module (CSM) – This is used in the customer support/call in center and it houses all the information on the complaint, when a customer calls in.
- The Service Module – This is used in the service center, and it houses all the failed product investigation results and the components replaced during service.

All these modules are used by different functional groups located all over the world. The modules are linked together and data from all the modules is accessible to cross-functional teams with the appropriate permission levels in the SAP system.

### *3.2 Error Coding System*

Prior to product launch, a comprehensive error coding system is set up to ensure that appropriate failure information is collected after product launch. These codes are available in the Customer Support Module and the Service Module in SAP.

The three types of codes used are "customer complaint code", "component code" and "cause code". The customer complaint code captures what the customer is complaining about or the failure mode of the system. The object code captures which component failed and which parts were replaced to fix the problem. The cause code captures what was the most likely cause of the failure. The design Failure Mode Effect Analysis (dFMEA), performed during the design phase is used as an input, while developing the complaint codes. Typically, the customer support analysts from the call-in centers fill out the customer complaint codes while the service technicians from the service/repair centers fill out the component codes and the cause codes. For example, if a customer calls in with a complaint that the Continuous Positive Airway Pressure (CPAP) medical device does not turn on, a complaint code of DNF – device non functional, will be selected by the customer support personnel. When the device is sent back to the service center, and the on-off rotary knob encoder is found to have failed due to insufficient solder on one of the contact pins; the component code of RKNF – rotary knob non functional, and the cause code of VWSI – vendor workmanship solder issue will be selected and logged into the service module of SAP.

### *3.3 Process flow diagram of a Product Monitoring System at a medical device manufacturer's facility*

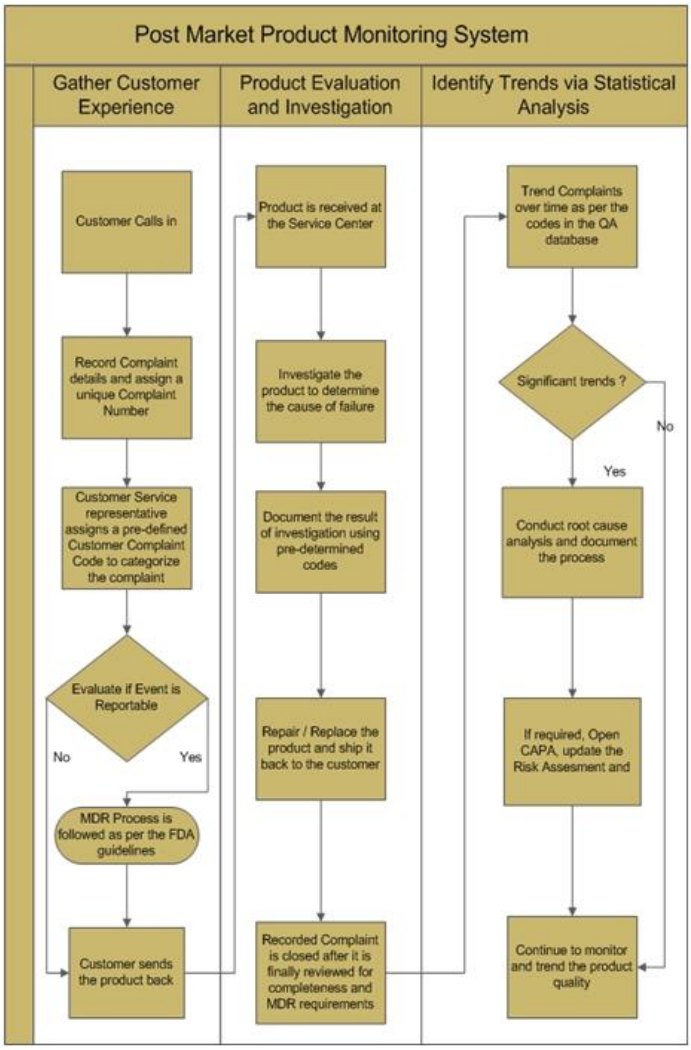


*Fig 1 – Post Market Product Monitoring Process Flow Map*

### *3.4 Gather Customer Experience*

After product launch, when a customer calls into the customer support center with a complaint, the customer support analyst gathers the following information; customer name, the product serial number (written on product), the model number (written on product), the reason for return, and whether the failure resulted in potential/harm/injury to an user. The analyst then gives the customer a unique complaint

number called the Return Authorization Number (RA#) that gives the customer the authorization to return the faulty product to the service center for a replacement. The six digit RA number is the key to the customer support module and the service module.

Based on the description of the failure mode or the reason for return, the customer support analyst assigns a customer complaint code and performs an initial assessment on whether the complaint is reportable to the FDA or not (based on guidelines in 21 CFR, Part 803). If the event is potentially reportable, a flag is set in the SAP database to ensure that every person handling the device is aware that it needs to be evaluated and documented from a safety perspective, using a custom set of forms designed specifically for potential FDA reportable issues.

### *3.5 Product Evaluation and Investigation*

When the failed product is received at the service center, the receiving technician pulls up the record for that particular device in the Service Module, using the unique return authorization (RA) number, and logs the "date received". The date and time for the product arrival at every station /step in the evaluation and repair process is recorded in the Service Module.

The product is then sent for decontamination in a restricted area. After decontamination, the product is sent to the investigation area where it undergoes several tests to verify functionality of the device. Results of these tests are compared to the results of the same tests run on the production floor, prior to shipping the device. All the production test results along with detailed information on every component that is assembled into each individual product are available in the electronic Device History Record (eDHR) Module of SAP.

After the evaluation is completed and the failed component(s) have been identified and replaced, the information is coded into the Service Module using the component code and the cause code. Complaints that are marked as potentially reportable events are verified to be either reportable or non-reportable. After a final check for completeness of evaluation and documentation, the product is either scrapped (if it is non-repairable) or repaired and sent back to the customer (if it is repairable).

### *3.6 Identify Trends via Statistical Analysis*

All the data collected, like complaint codes, component codes, cause codes etc are used for trending and identifying patterns in device, component, and process quality.

IBM SPSS Modeler, a data and text analytics software, is used to identify the customer complaint trends over time. Fig 2 shows a data mining model used to facilitate this analysis.

A time series graph derived from the model above is shown in Fig 3 below. This example shows an increasing trend of 'pressure fluctuation' complaints that are clustered around Oct 2005.

Once this trend is identified, a detailed root cause analysis is performed to find all the causes of 'pressure fluctuation' complaints in the month of Oct. Lean and Six Sigma tools like

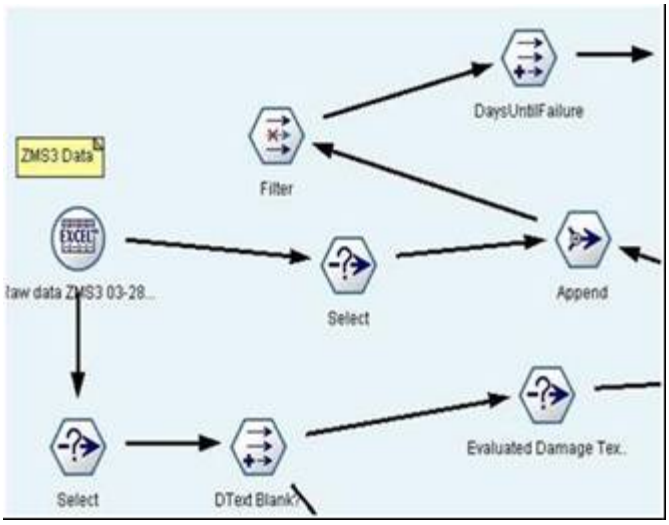


*Fig 2 – IBM SPSS Data Mining Stream*

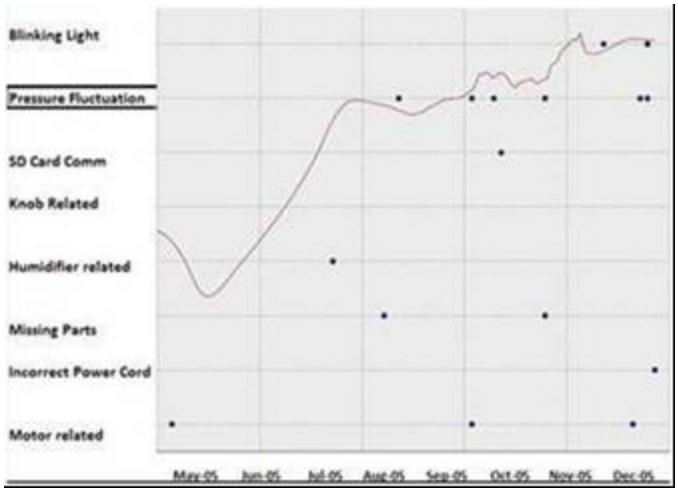


*Fig 3 – IBM SPSS time series model*

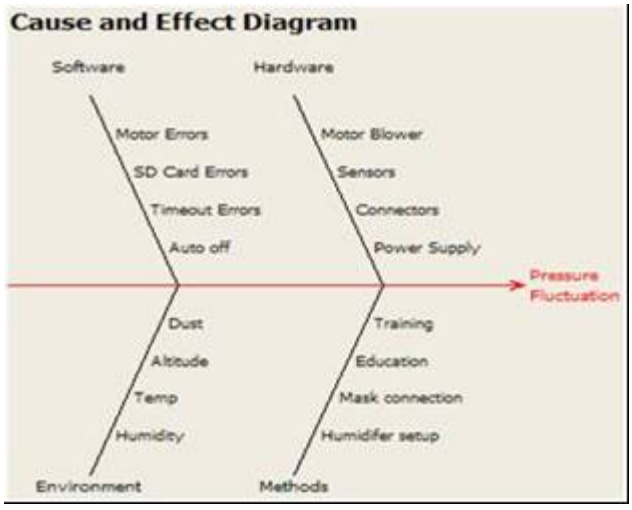


*Fig 4 – Cause & Effect diagram*

Cause & Effect diagram, Control charts, Gage R&R etc can be used to identify the root cause of the complaint. Fig 4 shows a portion of the Cause & Effect diagram for "pressure fluctuation" complaints.

During Cause and Effect analysis, an out-of-spec pressure sensor was identified as the cause of "pressure fluctuation" complaints. The eDHR records of all the devices that failed in Oct 05 were evaluated to identify trends in sensor data. It was discovered that most of the devices that failed in Oct '05 were manufactured in July 05 and that the pressure sensors in these devices came from two lots manufactured in May 05 at the sensor manufacturer's facility. Further investigation revealed that there had been a process shift during the manufacturing of the two out-of-spec lots. This resulted in the increased failure rate in Oct 05 of devices built in Jul 05 with the out-of-spec sensors. Data from Incoming Material module and eDHR module in SAP were used to correlate these sensors with the units they were used in.

The next step is to determine whether regulatory action such as Medical Device Reporting (FDA, USA), Medical Device Vigilance Reporting (EU), advisory notices, recalls and other actions are needed. This evaluation requires an assessment of the severity of the harm caused by the pressure fluctuations and the probability of occurrence of the failures. Reliasoft's Weibull++ software [4] is used to predict the failure rate of the affected units built in Jul 2005 (with the out-of-spec sensors). Table 1 below shows the Nevada Chart used as input for failure rate prediction.

| | Jun 05 | Jul 05 | Aug 05 | Sep 05 | Oct 05 | Nov 05 |
|---|---|---|---|---|---|---|
| May 05 | 12 | 33 | 44 | 34 | 35 | 44 |
| Jun 05 | 36 | 44 | 52 | 32 | 67 | 72 |
| Jul 05 | | 55 | 61 | 66 | 81 | 91 |
| Aug 05 | | | 31 | 44 | 95 | 101 |
| Sep 05 | | | | 31 | 68 | 71 |
| Oct 05 | | | | | 52 | 58 |
| Nov 05 | | | | | | 77 |

*Table 1 – Nevada Chart for failure rate prediction*

Table 2 shows the forecasted failures for the units built in July '05. The number of forecasted failures helps determine the occurrence level of failures, which in turn helps determine the risk level of the "pressure fluctuation" failures.

| | Dec 05 | Jan 06 | Feb 06 | Mar 06 | Apr 06 | May 06 | Jun 06 |
|---|---|---|---|---|---|---|---|
| May 05 | 48 | 49 | 49 | 50 | 50 | 51 | 51 |
| Jun 05 | 72 | 74 | 75 | 75 | 76 | 77 | 78 |
| Jul 05 | 85 | 87 | 88 | 90 | 91 | 92 | 93 |
| Aug 05 | 75 | 77 | 79 | 80 | 81 | 82 | 83 |
| Sep 05 | 42 | 44 | 45 | 46 | 47 | 47 | 48 |
| Oct 05 | 53 | 56 | 58 | 60 | 61 | 62 | 63 |
| Nov 05 | 33 | 38 | 40 | 41 | 42 | 43 | 44 |
| Total | **408** | **424** | **434** | **442** | **449** | **454** | **459** |

*Table 2 – Forecasted failures*

The risk assessment is updated (if necessary) to account for the new information from the field. New hazards are added or the severity or occurrence levels of existing hazards are updated.

In some cases, the FDA may ask a medical device manufacturer to perform a post market surveillance study to evaluate the efficacy and/or risk related to a medical device. In this case, data that is collected from the study is analyzed and trended using the tools mentioned above and the conclusion is submitted to the FDA for review.

## *4 CONCLUSION*

Having a robust post market surveillance program is a FDA requirement for medical device manufacturers', but it is beneficial to non-medical industry manufacturers as well. The concepts, processes and tools discussed in this paper, can be applied to both medical and non-medical fields.

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Vaishali Hegde is a Sr. Staff Engineer at Philips Respironics. She has 16 years of engineering and management experience comprising of reliability consulting, reliability application engineering, design and process engineering, testing, risk management and project management in the defense, aerospace, chip manufacturing, and medical industries. She received her BS in Electrical Engineering from West Virginia University. She has published articles, contributed a chapter to the Handbook of Performability book and presented papers at RAMS2006 & RAMS2010. She is a senior member of ASQ and is on the board of the ASQ Pittsburgh Chapter. She is also an ASQ-Certified Reliability Engineer.


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