Design of Methodology to Uncontrolled Documents Assessments for Quality Department

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Abstract *— A medical device company embarked on the journey of developing a program of control of possible human errors that can be applied in any place of manufacture. The project is based on the creation of a methodology to standardize documents not controlled for the change of the Department of quality control procedure. This provides a standard, simple and effective methodology towards the solution of problems. The creation of this methodology is essential. The initial objective of this project was to provide a program of prevention of Human Error through the development and design of tools and methodologies that can be applied in manual assembly and manufacturing processes. These tools would be designed and tested in all areas. Document control program, started with the current processes of manufacturing as a goal, but based on the obtained results will be applied to the new product introduction process.*

Key Terms *— DMAIC, Human Error, Medical Device, Uncontrolled Documents.*

PROJECT STATEMENT

Through the years, the standards require that invalid and/or obsolete documents should be promptly removed from all points of issue or use. Standards do not address the question of the use of documents controlled vs. uncontrolled, documents only invalid and/or obsolete documents. Therefore, make sure that the correct document is available and used only the correct version should be the key of any system of document control point. The industry must find a way to comply with requirements of federal agencies without adversely affecting the process, following the recommendations given. The use of uncontrolled documents may affect the quality of the product, because that in the case of an incorrect data can lead to malfunction.

RESEARCH DESCRIPTION

This project is based on the creation of a methodology in order to standardize the uncontrolled documents for control change procedure of the Quality department. The creation of this methodology is indispensable. This affects the processing of information that leads to an error or failures in the manufacturing of the product. For that reason, the company may is not complying properly with the regulations established by the Federal agencies, this being the main reason.

RESEARCH OBJECTIVES

The objectives of this research work are:

- Establish a procedure to work with the uncontrolled documents of Quality department.
- Verify that documents are obsolete / present disabled.
- Do standards documents with their numbers and identifications (IDs).

RESEARCH CONTRIBUTIONS

With the project implementation, the company that maintains a continuous flow of product, eliminate waste and improve customer satisfaction. At the same time, this provides proper control in the information system, which results in a suitable operating procedures.

LITERATURE REVIEW

To guarantee the quality of product or service, it’s necessary to maintain the accuracy and control the process. There is no easy way to adequately

control change in processes. Documentation control is a complex process. Not having a proper control system may also cause “complex” results. Control inadequate documentation exposes a company to liability actions by products, causes internal confusion, and in turn is a serious violation of the regulation of the system of quality (QS). To achieve a successful documentation, updates to procedures will be representative of the process; the equipment must comply with the appropriate requirements should be tested with appropriate standards. According to the section 820.30 Design changes [1]. CHANGE CONTROL. Manufacturing change control is usually implemented using a set of standardized procedures similar to the following:

- A change request might be originated by a developer, manager, reviewer, marketing representative, user, customer, quality assurance representative, or production personnel, and identifies a design problem which the requester believes should be corrected. Change requests are typically reviewed following the manufacturer's prescribed review process, and the request might be rejected, deferred, or accepted.
- If a change request is accepted and corrective action is straightforward, a change order might be issued on the spot to implement the change. The change order pertains to an explicitly identified document or group of documents, and specifies the detailed revision of the document content which will fix the identified problem.
- Often, the change request results in an assignment to developers to further study the problem and develop a suitable corrective action. If the change is extensive, wholesale revision of affected documents may be warranted in lieu of issuing change orders.
- Change requests and change orders should be communicated to all persons whose work might be impacted by the change.
- It may not be practical to immediately revise documents affected by a change order. Instead, the common practice is to distribute and attach a copy of the change order to each controlled copy of the original document.
- Change control procedures should incorporate review and assessment of the impact of the design change on the design input requirements and intended uses.
- A mechanism should be established to track all change requests and change orders to ensure proper disposition.

Change control activities and procedures apply to: design; components, including software; labeling and packaging; device manufacturing processes; production equipment; manufacturing materials; and all associated documentation such as quality system procedures, standard operating procedures, quality acceptance procedures and data forms, and products-specific documentation. Change control should also be applied to any production aids such as labeled photographs and models or samples of assemblies and finished devices.

As a process regulated and supervised by federal agencies, set the quality Department, must follow a structure for the compliance with the established procedures. The most critical procedures of the quality Department are the control of controlled documents. Controlled documents is a legal document that includes set up, monitor, and record quality in all aspects of documentation and quality control. The documentation of this sheet is important in order to comply with the appropriate documentation, since this affects the quality of the information and the existing compliance with federal agencies.

The process begins when determining the identification of the need for change; making, evaluating, and reviewing the change in the product or process; and revising and distributing the documentation is about half of the change control process the change also needs to be correctly implemented. Quality assurance and other designated personnel should make certain that the change is fully implemented during routine production, as shown by data and activities that

meet GMP (group manufacturing practices) requirements for [2]:

- Review of production records [820.80 (d) (2)]
- Acceptance of components, labels, materials, etc. [820.80]
- Assuring that quality assurance checks are appropriate and adequate for their purpose and are performed correctly [820.30 (d)], [820.181 (c)] and [820.80 (d)]
- Finished device evaluation [820.80 (d)]
- Collection of device history record data to demonstrate that the device is manufactured in accordance with the updated device master record [820.184]
- Making certain that only accepted product is distributed, used, or installed [820.80 (d) and 820.86].

The change procedure should cover these activities and specify that they are accomplished before the first lot of the changed devices is released for distribution. After the change is implemented, resulting components in –process items and finished devices should meet the new specifications established in the revised device master record (DMR) as shown by the data in the Device History Record. This agreement, of course, is assured by the change control procedure as well as the remainder of a manufacturer's quality system.

The device master record (DMR) is a compilation of records containing the procedures and specifications for a finished device [820.3 (j)]. The record contains the manufacturer's documentation for the device specifications and all other documentation required to procure components and produce, label, test, package, install, and service a finished device. Manufacturers are to prepare, control changes to, and maintain a device master record using the document control procedures outlined in 820.30 and 820.40.

For the medium to large company, a change control procedures is one of standard operating procedures (SOP's) used to produce and control documentation or control activities that result in documentation.

The manufacturers should develop and use a change control procedure that allows rapid changes, approvals, and implementation.

Controlling documents ISO – International Organization for Standardization Importance of Document Control.

- Helps ensure compliance with audits.
  - Document control generates most nonconformance in ISO 9001 QMS.
  - Some of most common reasons for FDA 483 Observation and Warning Letter Citations (2007).
- Essential to Risk Management.

The important point to consider is that all changes are made according to the approved company policy and procedure. Making uncontrolled changes is a violation of several sections of the QS regulations, including sections 820.30, 820.40, 820.70, 820.75 and 820.181. Also companies making uncontrolled changes are not operating in a state- of- control. Such a review should be part of the quality system audit.

Changes control records for the documents should cover:

- Identification of the entity being changed
- A description of the changes
- Identification of the affected documents
- Signature of the approving individual(s)
- The approval date and when the change becomes effective.

Revision Level

The way the revision level is to be incremented and which code should be used need to be covered by the change procedure for: components including software, assemblies, and devices; and associated documentation such as labeling, process procedures, and assembly drawings. It is common practice to use numerical revision level during pilot production and letters during full scale production.

Validation

Each changed device, accessory, labeling, packaging, and process should be thoroughly verified and/ or validated by the appropriate department. Then the test results and all information related to the change should be reviewed by the change control board or other designated review group. This procedure is the same as needed for designing and introducing a new product or process into production and is detailed in section 820.30, Design Controls. Changes that only modify documents and do not change any design aspect of a device or process are performed according to 820.40 (Code of Federal Regulations). The change control procedure should be state the details of the evaluation and review process or, as appropriate, refer to the company control procedures. The change control procedure should define the responsibilities of the various departments and members of the review board.

Updating documentation

The change procedure should cover updating of primary and secondary documentation such as instruction manuals. Usually there are no problems with updating or revising primary documentation in fact that is a major reason the given changes order is being processed. In contract, it is rather easy to forget that related secondary documents such as component drawings, instruction manuals or packaging require revision if affected by a given change. The use of a good change control form can alleviate this problem.

Documentation Distribution

Revised documentation should be distributed to persons responsible for the operations affected by the change and old documents removed and filed or discarded, as appropriate. After a document has been approved, these documents shall be available at all locations for which they are designated, used, or otherwise necessary, and all obsolete documents shall be promptly removed from all points of use or otherwise prevented form unintended device tended use. This means current documentation shall be accessible to company employees [820.40 (a)]. Supervisors should be vigilant in overseeing the flow and use of documentation, especially if a change is being phased in, because both the old and revised documentation may exist in a given department during the transition period.

Regulatory Submissions

Modifications to devices or manufacturing processes should be made and covered under the quality system change control procedure as described herein. Such changes may also require a premarket notification [807.87 (g)] or premarket approval (PMA) supplement (814.20) depending on the classification of the device. The change order or control form is a convenient document for reminding employees that regulatory submissions should be considered when making at change.

Medical devices Quality management systems requirements for regulatory purposes –BS in ISO 13485:2012.

Documentation Requirements [3]

The quality management system documentation shall include:

- Documented statements of quality policy and quality objectives
- A quality manual
- Documented procedures required by the International Standard
- Documents needed by the organization to ensure the effective planning, operation and control of its processes
- Records required by this International Standard
- Any other documentation specified by national or regional regulations.

The extent of quality management system documentation can differ from one organization to another due to

- The size of the organization and type of activities
- The complexity of processes and their interactions
- The competence of personnel

METHODOLOGY

In order to achieve the proposed objectives, this section provides an overview of procedure and methodology that will be applied in the design project. The project methodology to be used is DMAIC improvement strategy coming from Six Sigma principles. DMAIC is an acronym that has five phases: Define, Measure, Analyze, Improvement and Control.

- **Define Phase:** This phase consists of defining the scope, objectives and connected projects. Critics will be used for the quality (CTQ) tools, in order to describe the process and identify issues.
- **Measure Phase:** The objective of this phase is the compilation of aspects of the current process and relevant data. In addition to the identification of the potential factors that may affect the process. You will use the data collection process. Use tools are evidence in photograph of the document laid down out of control in the area.
- **Analyze Phase:** This phase is to identify the root causes in order to validate the relevant data. The key components of this phase will include cause-effect.
- **Improvement Phase:** The objective of this phase is to optimize the current process. Key components of this phase include lean manufacturing tools and techniques of standardized work automation.
- **Control Phase:** This phase include design and document the new controls and procedures, to hold the control. Key components for this phase are the Visual work places, exercises periodical audit and training process to monitor success.

RESULTS AND DISCUSSION

This chapter present the problem analysis and improvement results using the Lean problem solving methodology, DMAIC tool.

Define Phase

The project goal pursues to control the obsolete and invalid documents. The Project scope include a checklist with instructions of what the team will be removing from the manufacturing rooms. The indication of deliver the checklist to the responsible leaders during the manufacturing meetings. And the instruction of posting assessments to the manufacturing areas.

The Project team members include the Sr. Compliance Analyst, Compliance Analyst, RA/QA and the Quality improvers. The role of the team members consists in complete a tour of the manufacturing areas, identify and select the necessary documents by the company to ensure the effectiveness of the planning, operation and control of our processes and their respective activities, performed a checklist with instructions of what the team will be removing from the manufacturing rooms, deliver the checklist to the responsible leaders during the manufacturing meetings and Post assessments to the manufacturing areas. All this activities will be completed as part of the DMAIC measure phase. The measure phase has an expected duration from three week to a month, in order to complete the project goal of three months. The satisfactory completion of this plan, can serves as model for other manufacturing areas. As a guide for team members and managers to see whether the project is conducted in the right direction as proposed and the goals has been reached in time, a project Check List was performed.

Measure Phase

The medical device company consists of 2 areas of manufacturing which are distributed among 5 different products, each installation has its respective products as shown in Figure #1.

As we can see the business 1 is distributed in 3 different units or products. While in the business 2 is distributed in two different units.

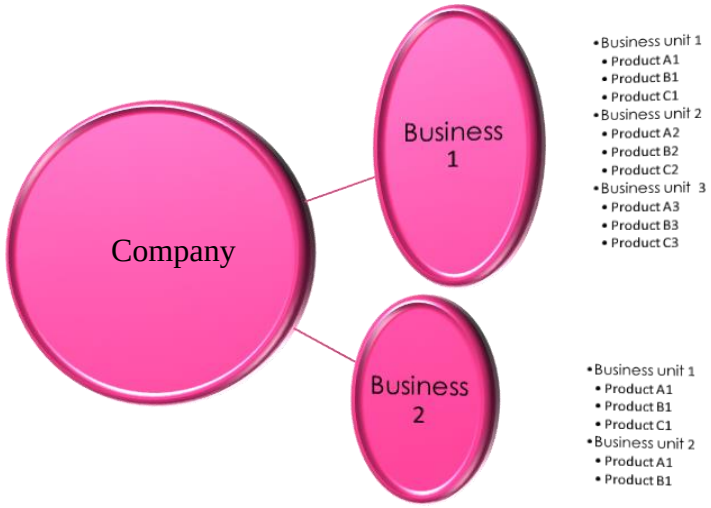

Figure 1
Areas Distributed

As this information was completed after several assignments, where the team members proceeded to visit the area of manufacture to verify which documents were obsolete / invalid were present. There are a series of documents in the manufacturing areas which were not subject to the requirements. Then those documents were displayed in areas of distribution.

For the Business 1 division, the Equipment ID / Components Visual Aid are shown in the figure #2. Figure #3 shows the Monitoring, Production forms and / or Tasks to do for reference. Figure #4 shows the Defects codes, Tables from procedures, and visual Aid for filter changes are shown in the figure #5.

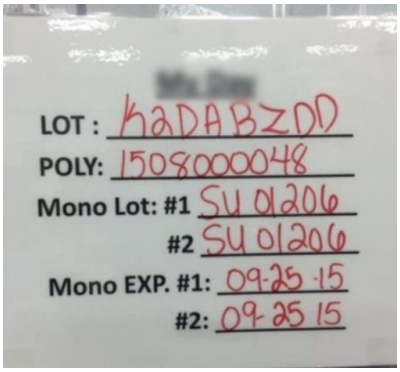

Figure 2
Equipment ID / Components Visual Aid

Figure 3
Monitoring, Production Forms and / or Tasks to do for Reference

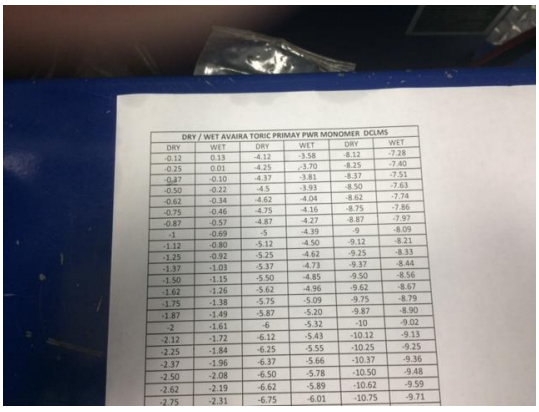

Figure 4
Defects Codes, Tables from Procedures

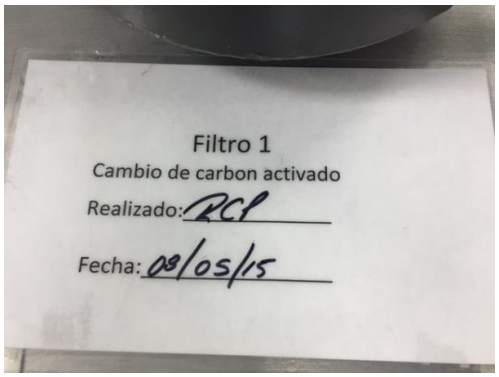

Figure 5
Visual Aid for Filter Changes

For Business 2 unit, the Equipment ID / Components Visual Aid is show in the figure #7. Figure #8 shows the Monitoring, Production forms and / or Tasks to do for reference. Figure #9 shows the Tables from procedures.

Figure 6
Equipment ID / Components Visual Aid

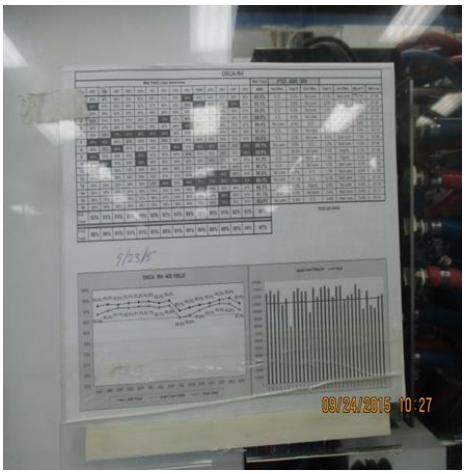

Figure 7
Monitoring, Production Forms and / or Tasks to do for Reference

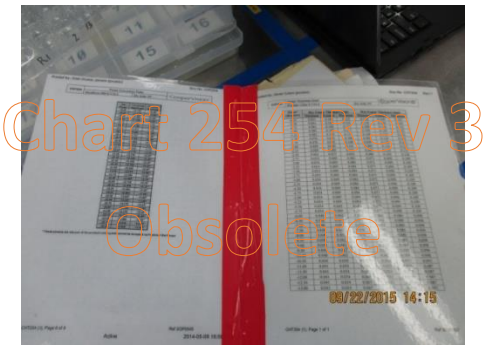

Figure 8
Tables from Procedures

Analyze Phase

The focus in this phase is the identification of opportunities for the further improvement within the current uncontrolled documents. The first step was to analyze all the collected information and/or areas. Then, understand all the possible causes that affect the obsolete documents through a fishbone analysis fishbone, and finally set up priorities among them, identifying the causes.

According to the manual of medical devices, each manufacturer shall establish and maintain procedures to control all documents. The following criteria was used for the analysis of the identified documents. The procedures shall provide for the following:

- **Document approval and distribution:** approval, including the date and signature of the individual(s) approving the document, shall be documented.
- **Document changes:** Changes to documents shall be reviewed and approved by an individual(s) in the same function or organization that performed the original review and approval, unless specifically designated otherwise.

Documents that comply with the above requirements were selected for use throughout the plant manufacturing as a standardized document. Cause - effect analysis were performed as shown in figure #9. They were carried out to understand all the possible causes that affect the quality of the products.

The documents found in the manufacturing area did not have the corresponding validation. The use of these documents can affect the quality of the product, either by obtaining data obsolete or incorrect, since in the case of an incorrect data can be bad "quality" product.

The main possible causes were identified in the fishbone diagram. The ones that affects the quality of the product were selected to be evaluate and classify under the fallowing 4 categories:

- High Impact– Low Difficultly
- High Impact – High Difficult
- Low Impact – Low Difficultly
- Low Impact – High Difficult

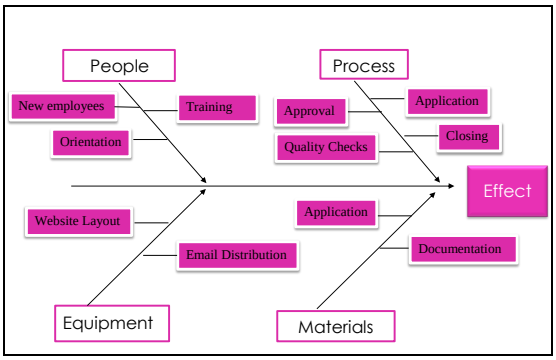

Figure 9
Fishbone Diagram

The High/ Low Impact factors were defined in terms of the effect productivity. As well, the High/ Low Difficultly factor were defined in term of time/effort to implement, and quality risk. The figure #11 shows the analysis performed and the selected causes fallowing the previous app

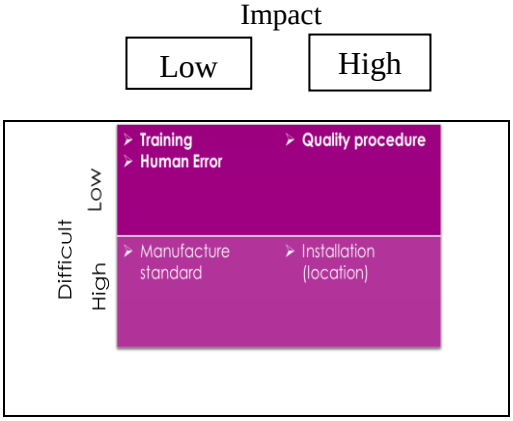

Figure 10
Categorized Analysis

After discussing with the team members, there were five primarily aspects selected and categorized as shown in Figure #10. The primarily focus on the selection pursues the initiative considered has low difficulty and high impact. Therefore, quality procedures, were selected as causes of process, these can be improved with less implementation time and effort required.

Improvement Phase

To control the documents it is necessary to have a procedure that determines the guidelines.

Once the documents were identified in the production area, they were analyzed. They were checked against the relevant control regulations, like the authorization or validation. Once identified, a series of questions were completed to determine if were necessary to keep them in the manufacturing area permanently. In some cases there are documents that if they are required to have it permanently and others simply can be used depending on the need. Taking into account that employees claim that the documents are a guide necessary to know the respective performance. Consistent with this situation, the team members understand that is was recommendable to standardize documents with their own IDs and numbering.

Once selected documents update, continues to train staff responsible for each area. Then informs employees the documents that will be placed in the area of manufacturing so that the entire plant will be properly regulated and in full equality. The documents that should not be permanent in the area of manufacturing it is once they are used and verified by the supervisor, these documents are they discarded.

Control Phase

The purpose of the DMAIC control phase is to provide a control plan to prevent that initiatives and solutions are kept so that they can be controlled and avoid problems in the future by providing a sustainable benefit of quality. The control plan determined included:

- Visual aid in order to remember the correct processes.
- Constant training and monitoring.

These controls must be put in place to maintain and assure to keep the key requirements. As mention in the improve phase, the team determined that a Controlled Document Header must be included in the selected documentation. Figure 11 shows example of controlled document header.

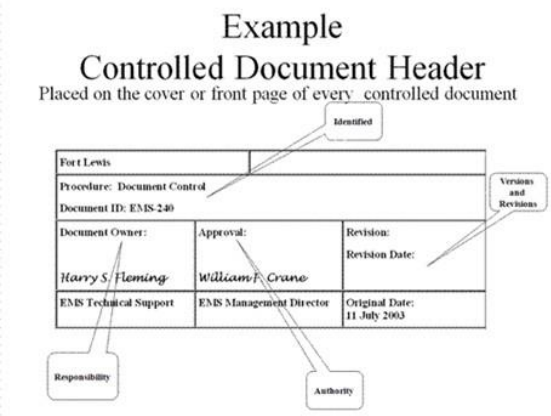

Figure 11
Example Controlled Document Header

It was created with the objective of standardizing and updating the equipment in a simple and active manner. The form allows for a continuous evaluation of the data systematically. The handling of this form will be added and which will be part of the existing medical devices company manual.

Medical device manual contains brief information on document control, record control and documentation requirements. The process begins when the quality improver intervenes auditing the area. Then, the improver must fill the General requirements form. Once the irregularities were identified, the team should notifies the supervisor of the area. The quality supervisor in this case, RA/QA senior checks all possible data causing effects in the process. The Supervisor fills the document, evaluates and approves. Once done tours and assessments by the areas of manufacturing, the information is entered into the database. Then, a visual aid to remember settings, facilities and/or the affected equipment must be added. The controls were carried out in order to maintain and ensure a standard work, which is a key to the continued improvement of the process. In addition, a successful implementation includes the constant training and supervision.

CONCLUSION

The DMAIC tool provides a structured way for business improvement with a road map for solutions. After follow-up analysis, the medical device company had standardized, that took them to fewer errors and better quality. In order to make a standardized work plan, team designed the form based on the SOP. Due to the successful implementation of the project, this achievement will be extended to all the other areas of the company's medical devices.

In conclusion, due to these results; this program will be incorporated within the Company Quality Document System, to be used by all sites; reaching to reduce the probability of human error within their manufacture process.

The RA/QA department of the medical device company plan is to do more consecutive inspections using a monthly checklist as show in figure #1, in different manufacturing areas so as to control the process and ensure product quality.

REFERENCES

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