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1. Purpose/Policy

The procedure communicates the process for the identification, development, and implementation of strategic and operational initiatives to achieve MDSAP's vision and objectives as described in the MDSAP P0001 Functional Statement document.

1. Continual Improvement of the MDSAP process: To identify and implement process improvements that enhances the quality and consistency of the Medical Device Single Audit Program (MDSAP) process.

2. Continual Improvement of the MDSAP Quality Management System (QMS): To evaluate the Quality Management System for its effectiveness; to identify areas where changes are needed; to revise the process to reflect QMS changes.

2. Scope

This procedure applies to all MDSAP participants at all levels.

Continuous Improvement is more of a philosophy than a process or system. It requires everyone as a participant to adopt, as part of their normal work, a mind set of continuously looking for ways to improve processes and systems, i.e. to make them more efficient and effective.

3. Definitions/Acronyms

Continual Improvement CI): Recurring activity to enhance performance (ISO 9000:2015)

- Note: the process of establishing objectives and finding opportunities for improvement is a continual process through the use of audit findings and audit conclusions, analysis of data, management review or other means and generally leads to corrective action or preventive action.

Continuous Quality Improvement (CQI): A philosophy and attitude for analyzing capabilities and processes and improving them repeatedly to achieve customer satisfaction. (ASQ-Quality Glossary)

Efficiency: relationship between the result achieved and the resources used (ISO 9000:2015)

Effectiveness: Extent to which planned activities are realized and planned results are achieved. (ISO 9000:2015)

Objective: Result to be achieved (ISO 9000:2015)
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- Note: Objective evidence may be obtained through observation, measurement, test and other means.

Process: Set of interrelated or interacting activities that use inputs to deliver an intended result. (ISO 9000:2015)

Improvement: Activity to enhance performance (ISO 9000:2015)

Process Improvement: The application of the plan-do-check-act cycle (see listing) to processes to produce positive improvement and better meet the needs and expectations of customers. (ASQ-Quality Glossary)

4. Authorities/Responsibilities

MDSAP Regulatory Authority Council (RAC) Chair person:
- Ensure the procedure is followed and enforced within all MDSAP participants.

MDSAP Regulatory Authority Council (RAC):
- Ensure existence of a positive climate, which encourages continual improvement within MDSAP participants.
- Reviews the preventive action reports and allocates resources needed to implement preventive action, as applicable. Additionally, reviews audit reports, corrective action reports, and customer complaints/ feedback for opportunities to improve processes, services, products, and the quality management system.

MDSAP participants:
- Identify opportunities for improvement in work processes, services and

products.

5. Procedures

Continual improvement of the effectiveness and efficiency of the MDSAP Quality Management System is accomplished through the use the quality policy, quality manual, quality objectives, audit results, analysis of the data, corrective and preventive actions and management reviews.

MDSAP has created an environment that encourages all participants to actively seek opportunities for improvement of performance in processes, services, and products in order to improve the satisfaction of all interested parties.

1. Continual Improvement of the MDSAP Process:
The MDSAP QMS Quality Manual embodies an organizational commitment to continual improve the MDSAP process. Even after the Quality Management System is implemented and well developed, the feedback and improvement cycle needs to continue. In order to identify future areas for improvement in the MDSAP process, the process will continue to be analyzed carefully through systematic oversight, and feedback will be received from both customers (internal/external) and stakeholders to identify new issues and solutions to address these issues.

  a. Analyze the Current Process - Internal (technical) audits and process audits provide a mechanism to analyze the MDSAP and QMS processes from both technical and management perspectives. These audits assist in documenting what is happening in the process at that time and how well it is being done. The result can be used to identify areas for improvement in the MDSAP process. In addition to the use of those audits, MDSAP teams and participants can provide suggestions on how to improve the quality or efficiency of the process from their unique perspective using various mechanisms designed to obtain candid feedback. This feedback may reflect what is going well in the MDSAP process, as well as ideas about what could be improved.

  Identification of customer needs is a part of the Quality Management System. For example customers could be asked how well the current MDSAP process is meeting their needs and where deficiencies are perceived. This input could be used as a basis to periodically asses how well their needs are being met and to determine ways the process can be improved to better meet customer expectations.

  Over time, customer needs, or their ability to express their needs, may change. Changes that result in improvements in the MDSAP process

over time will become routine, and new expectations will arise. By periodic assessment of customer satisfaction, and determining new requirements, the MDSAP process can continue to improve and evolve.

b. Identify the Issues/Problems - The input from internal and external parties involved in the MDSAP process and analysis of metrics should yield a list of issues that would benefit from further evaluation. Input may be submitted through written documentation or oral communication. Each issue that is identified through a source or performance metric has a reason behind its existence. In some cases the issue has a particular root cause such as a type of barrier not allowing to perform their job better. By understanding the correct root cause, the solutions are more likely to be effective.

c. Develop Solutions to the Issues/Problems - If root causes of issues and barriers to better performance in the MDSAP process are not identified, it will be difficult to develop potential solutions that will work to improve the process. Because multiple issues may exist, a formal process may be needed to prioritize which issues to address. A team or focus group approach can be used to concentrate on developing particular solutions for an issue.

Once a solution has been evaluated by the team/focus group, metrics will be identify that can be tracked and used to determine whether or not the solution is effective. The metrics will be carefully chosen so they will reflect improvements directly related to the original issue and the solution being implemented. Information from these metrics can put in place the structure for continual improvement of the action/solution taken.
After the implementation of the solution has begun, the metrics will be monitored on a regular basis. The metrics will reveal whether or not the objectives of the solutions are being met. If the objectives are not being met, then the team/focus group will review the results and determine areas for improvement. It is possible the solution is not being implemented correctly, the solution is not a good choice, or the solution focuses on resolving the wrong problem.

Note: This philosophy follows the traditional quality improvement approach of plan-do-check-act as described in the MDSAP QMS G0001 Implementation of a Quality Management System within MDSAP. For further information use this document for your continual improvement process and apply to all procedures, policies, forms, and processes that are a part of the Path of Workflow.

2. Continual Improvement of the MDSAP Quality Management System (QMS)

Continual improvement is essential in a quality management system. Two

points that are particular important: 1) <u>Create constancy of purpose for improvement</u> – the message here is that there is a need to be constantly working toward making the process better; 2) Improve constantly and forever – this statement points out that continual improvement will always be a goal. Perfection is never achieved, but we try to get as close to it as possible. Process improvement is something that is never finished but rather continues on "forever".

MDSAP Quality Management System processes can be routinely analyzed to identify issues that affect the quality and consistency of the MDSAP products. In the same fashion, the QMS itself should be subject to continual scrutiny and improvement. Periodically, the QMS procedures, quality manual need to be reviewed to determine if they contain an effective and contemporary set of tools for ensuring the quality of the MDSAP process. Whenever improvements are being made to the MDSAP process, it is important to ensure that the quality management system reflects these changes as appropriate. But even in the absence of significant changes to the MDSAP process, the quality management system should be routinely revisited to determine which parts of it are working, and which should be improved, discarded, or replaced with a better tool. The following questions can be used to evaluate the effectiveness of the QMS initiatives:

- What new approaches were implemented?
- How were these approaches deployed?
- What effect did they have on performance metrics?
- How lessons learned were integrated?

At a minimum, the QMS should be formally revised and reissued every five years. It is likely that in the first few years of its implementation, the QMS may need to be revised more frequently, based on lessons learned.

3. <u>Tools that Support Continual Improvement</u>

- Tracking of the performance metrics
    - o Evidence of performance
    - o Identification of areas for potential improvement
- Analysis of process and technical audits
    - o Identification of targets for process improvements
- <u>MDSAP QMS</u> Process Improvement
    - o Analysis of current process
    - o Identification of issues
    - o Development of solutions
- <u>MDSAP</u> Specific Examples
    - o The definition of new or more challenging quality objectives by the RAC, as a result of the analysis of the process performance.

o The issuance of document change requests to address the inaccuracy or obsolescence of a document.
o The initiation of corrective action to address the cause of a single Nonconformity or a trend of Nonconformities.
o The initiation of projects to develop and implement new initiatives typically requiring multiple expertise or significant resources.
o The definition of action items typically as an outcome of a RAC meeting or a MDSAP operational meeting, typically requiring limited team work and limited resources.

6. Forms

MDSAP QMS F0013.1 Concern and Resolution Form

7. Reference Documents

MDSAP QMS P0005 - Management Responsibility and Management Review Procedure
MDSAP QMS P0008 - Internal Audit/Self Assessment Procedure
MDSAP QMS P0009 - Corrective Action (CA) Procedure

8. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2013-07-15	Initial Release	Liliane Brown
002	2016-02-02	Section 6 -Forms: page 6, 2 forms were made obsolete QMS F0009.1 (CAPR) and QMS F0011.1 (CF). Replaced with QMS F0013.1 Concern and Resolution Form	MDSAP QMS Team
003	2016-10-11	Revisions were made mostly in section 3 Definition/Acronyms to reflect the ISO 9001;2015/ISO 9000:2015 revisions	Liliane Brown, USFDA

Version 003
Approval

Approved: <u>Signature on file</u>   Date: <u>2016-10-24</u>
             CHAIR MDSAP RAC