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Approval Sign-Off Sheet

1. Purpose/Policy

Preventive Actions are proactive processes for the improvement of the Quality Management System and the avoidance of problems or complaints. The procedure establishes the process to identify and react to potential nonconformities in the MDSAP Quality Management System. The cornerstone of preventive action is written and retrievable documentation of actions taken and follow-up monitoring to determine that preventive actions have been implemented, documented, and effective.

2. Scope

This procedure applies to the MDSAP Quality Management System (QMS) where any aspect of work has the potential to not conform to MDSAP QMS requirements, i.e. policies, procedures, work instructions, etc.

3. Definitions/Acronyms

Cause: An identified reason for the presence of a defect or problem. (ASQ – Quality Glossary)

Correction: Action to eliminate a detected nonconformity. A correction can be made in conjunction with a corrective action. (ISO 9000:2005)

Corrective Action (CA): Action to eliminate the cause of a detected nonconformity or other undesirable situation in order to prevent recurrence. There can be more than one cause of a nonconformity. (ISO 9000:2005)

Fitness-for-Use: A term used to indicate that a product or service fits the customer's defined purpose for that product or service. (ASQ-Quality Glossary)

Nonconformity: Non-fulfillment of a requirement. MDSAP specifically in this program what are considered “direct” and “indirect” nonconformities to give some priority for corrective actions. (ISO 9000:2005)

Preventive Action (PA): Action to eliminate the cause of a potential nonconformity or other undesirable potential situation in order to prevent occurrence. There can be more than one cause for a potential nonconformity. (ISO 9000:2005)

Process: Set of interrelated or interacting activities which transform inputs into outputs. (ISO 9000:2005)

Product: Result of a process = service meaning the result of at least one activity necessarily performed at the interface between the supplier and customer and is generally intangible. (ISO 9000:2005)

Quality Management System – (QMS): To direct and control an organization in this case MDSAP with regard to quality. (Organization meaning a group of people and facilities with an arrangement of responsibilities, authorities and relationships.) (ISO 9000:2005)

Root Cause: A factor that caused a nonconformance and should be permanently eliminated through process improvement (ASQ-Quality Glossary)

Root Cause Analysis: Is a collective term that describes a wide range of approaches, tools, and techniques used to uncover causes of problems. (ASQ-Quality Glossary)

4. Authorities/Responsibilities

CA/PA System Manager: (*This role will be filled by the RAC Chair. The CA/PA System Manager has overall responsibility for CA/PA system management.)*

- Identifies preventive actions, if any, in management review.
- Assigns preventive actions to designated PA Assignee.
- Reviews and approves preventive actions

PA Assignee:

- Initiates, performs, and/or oversees preventive actions.
- Assigns preventive actions to appropriate person, if necessary.
- Reviews preventive actions initiated by the appropriate person.

CA/PA Administrator:

- Verifies implementation of preventive action plans.
- Maintains preventive action plans and documentation.

- Maintains the Concern and Resolution Form database.
- Closes preventive actions.

Note: All MDSAP members should be able to identify/suggest preventive actions, and initiate/perform identified preventive actions.

5. Procedures

PREVENTIVE ACTIONS

1. Preventive action plans are part of a proactive process for improvement rather than a reaction to problems or complaints. Preventive action includes the use of sources of information such as processes and work operations which affect quality, audit results, quality records, and complaints to detect, analyze and eliminate potential causes of nonconformities.

2. Preventive action includes the use of measurable quality objectives and requirements, validation and review processes, on-site reviews, audits and management review, feedback and complaints, suggestions, quality management system requirements, and the use of International Organization for Standardization (ISO) requirements*. (Only as definition, not procedures)*

3. Documented investigation using the MDSAP QMS F0013.1 Concern and Resolution From. This form is initiated if a potential nonconformity is identified from any of the above processes.

4. The preventive action process consists of:
   - Reviewing potential problems.
   - Deciding the potential cause of problems.
   - Determining the course of action to eliminate the problem from occurring. Putting the plan into action.
   - Ensuring or verifying the action solved the potential problem or is effective over time.

5. Preventive actions or potential nonconformities can be identified in the Management Review process by analyzing the information reviewed for unacceptable trends.

6. If a preventive action is identified and approved, a preventive action plan should be developed to address the problem. If the preventive action is not approved, no further action is taken.

7. The investigation, evaluation, and implementation are documented using the MDSAP QMS F0013.1 Concern and Resolution Form.

8. Preventive actions are closed when the results of the investigation are approved and the action has been implemented. Preventive actions are appropriate to the significance of the potential problems.

   Note: The CA/PA Administrator is responsible for follow-up and verifying the action plans are completed by the designated individual that is responsible for development of the preventive action plan.

9. Monitoring the information and effectiveness of the preventive action may be accomplished by any one or more of the following:
   - Process charts.
   - Performance measurements and training.
   - Customer inputs.
   - Employee feedback and inputs.
   - Audits and management reviews and
   - Management meetings.

   Note: Preventive actions are closed by the CA/PA Administrator after the follow-up has been approved.

6. Forms

MDSAP QMS F0013.1 Concern and Resolution Form

7. Reference Documents

MDSAP QMS P0005 - Management Responsibility and Management Review Procedure
MDSAP QMS P0006 - Control of Nonconforming Processes and/or Services Procedure
MDSAP QMS P0008 - Internal Audit/Self Assessment Procedure
MDSAP QMS P0011 - Complaint and Customer Feedback Procedure

8. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2013-07-15	Initial Release	Liliane Brown, USFDA
002	2015-12-30	Updated Section 4 Authorities/Responsibilities by removing project manager. Updated Section 5 Procedure to add overall role and responsibilities and to reflect the changes as listed in the MDSAP QMS plan.	Liliane Brown, USFDA
003	2016-01-27	Section 6 Forms: Removed QMS F0006.1 NCR and QMS F0009.1 CAPR and replace with form F0013.1 Concern and Resolution	Liliane Brown, USFDA

Version 003

Approval

Approved: _____Signature on file_____ Date: 2016/01/27
MDSAP Team Leader