

 <b>Responsible Office/Division</b>	<b>Document No.:</b> MDSAP QMS P0007.004	<b>Page:</b> 1 of 7
	<b>Version Date:</b> 2016-10-11	<b>Effective Date:</b> 2013-07-15
<b>Title:</b> MDSAP QMS Control of Quality Records Procedure		<b>Project Manager:</b> Liliane Brown, USFDA

## Table of Contents

1. Purpose/Policy
  2. Scope
  3. Definitions/Acronyms
  4. Authorities/Responsibilities
  5. Procedures
  6. Forms
  7. Reference Documents
  8. Document History
- Approval Sign-Off Sheet

### 1. Purpose/Policy

To control records generated by the Medical Device Single Audit Program and Quality Management System (QMS) processes.

### 2. Scope

This outlines the procedure for controlling records related to the MDSAP Quality Management System. This procedure addresses identification, access, filing, storage, retention, and disposal of records.

### 3. Definitions/Acronyms

Controlled Copy: A controlled copy is a formal copy of the latest, correct issue (approved version) of a document; an identified issue of a document to an individual or location of record. A controlled copy must be officially tracked, updated and stored for use.

Data: Facts about an object. (ISO 9000:2015) .  
(A data file is a set of collected factgs and is related numeric, graphic or textual information that is organized in a strictly prescribed form and format. ASQ-Quality Glossary)

MDSAP QMS Control of Quality Records Procedure	Document No.: MDSAP QMS P0007.004	Page 2 of 7
--	--------------------------------------	-------------

Disposition: The action taken regarding records no longer needed for current Government business. These actions include transfer to agency storage facilities or Federal Records Centers (FRC), transfer from one agency to another, transfer of permanent records to a third party location or to the National Archives, and disposal of temporary records. (USFDA)

Electronic record: Electronic record, as defined in the National Archives and Records Administration (NARA) regulations (36 CFR 1234.2), means any information that is recorded in a form that only a computer can process and that satisfies the definition of a Federal record per the *Federal Records Act* definition. Federal electronic records are not necessarily kept in a “recordkeeping system” but may reside in a generic electronic information system or are produced by an application such as work processing or electronic mail. Electronic records include numeric, graphic and textual information. (National Archives and Records Administration (NARA) regulations (36 CFR 1234.2)) (USFDA)

Federal Record: Records or Federal Records are defined in 44 U.S.C. 3301 as including “all books, papers, maps, photographs, machine readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the United States Government under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, function, policies, decisions, procedures, operation or other activities of the Government or because of the informational value of the data in them (44 U.S.C. 3301).” (Further explanation of this definition is available § 1222.10). (Federal Records are defined in 44 U.S.C. 3301) (USFDA)

Form: A document used to facilitate procedural implementation or document procedural objectives. Forms become a record once filled out. (National Archives and Records Administration (NARA))

Non-record: Documentary materials excluded from the legal definition or records or not meeting the requirements of that definition. Copies of memoranda or letters that were sent for information rather than action or messages and/or attachments for whose retention you are not responsible. Non-record may include extra copies of documents kept only for convenience of reference, stocks of publications and or processed documents and materials intended solely for reference. (National Archives and Records Administration (NARA))

Permanent Records: Records appraised by NARA as having sufficient historical or other value to warrant continued preservation beyond the time they are needed for administrative, legal, or fiscal purposes. Once transferred to another location such as NARA, they are under their legal custody. (National Archives and Records Administration (NARA))

MDSAP QMS Control of Quality Records Procedure	Document No.: MDSAP QMS P0007.004	Page 3 of 7
--	--------------------------------------	-------------

Record: Document stating results achieved or providing evidence of activities performed. (ISO 9000:2015)

Note:, records can be used, for example, to formalize traceability and to provide evidence of verification, preventive action and corrective action. Generally records need not be under revision control,

Retention Period: The length of time that records are to be kept. (National Archives and Records Administration (NARA))

Retention Schedule: A document that describes agency records establishes a period for their retention by the agency and provides instructions for what to do with them when they are no longer needed for current government business. (National Archives and Records Administration (NARA))

Uncontrolled Copy: An informal copy of a document for which no attempt is made to update it after distribution. Copies of documents made by users (in paper or electronic form) are considered “uncontrolled copies”. The responsibility of making sure the uncontrolled copy is the most current approved document is with the user of the document.

#### **4. Authorities/Responsibilities**

MDSAP Regulatory Authority Council (RAC) Secretariat ensures that records are maintained appropriately. (see MDSAP QMS P0002 Document Control and Approval Procedure for additional information)

MDSAP team is responsible for using the proper and approved forms and templates, and for following record control procedures.

Note: The authority and responsibility for maintaining mandatory records are listed in the MDSAP QMS P0002 Document Control and Approval Procedure and MDSAP QMS Master List document.

#### **5. Procedures**

Records are maintained to provide evidence of the conformity, implementation, and effective operation of the quality management system and other business activities of MDSAP. All records are required to be legible, accurate, readily identifiable and appropriately retrievable. MDSAP teams are required to maintain records (electronically or if needed hardcopy) to assure that we are in compliance with the federal records management regulations and policies by promoting the management of records throughout their life cycle in an economical, efficient and effective manner.

This process applies to the MDSAP team – FDA and for the participating MDSAP

MDSAP QMS Control of Quality Records Procedure	Document No.: MDSAP QMS P0007.004	Page 4 of 7
--	--------------------------------------	-------------

team (Australia, Brazil, Canada and Japan) recommended to follow their own government regulations.

### **Records and Maintenance**

All MDSAP teams will complete records for all work activities performed and maintain records as well as assure information is documented and legible. MDSAP records (e.g. reports, correspondence, quality records), include but not limited to:

- Contract Audit Activity and records
- Emails for official business
- Electronic records such as Quality Management Information
- Memorandums
- Meeting minutes
- Records such as corrective and preventive actions, complaints & feedback, audit and assessment results, document changes requests, transmittals notices, master lists, and standard operating procedures.
- Training records
- “Purchasing records related to MDSAP-FDA”
- Reports such as audit reports, and management review reports
- Work plans

Note: personal papers are not government owned and are not considered MDSAP record. Personal papers are documentary materials belonging to an individual that are not used to conduct government business. Regulatory notes are not considered personal papers.

### **Record Identification**

- Records are identifiable to the MDSAP entity, process/product, person or event to which they pertain, and
- Records are dated and identify the person who established the record.

### **Recording and Error Correction**

- All work performed is recorded legibly
- Electronic records must have an audit trail to document the change(s), and
- Data or information is not discarded without explanation. To discard, the data or information is crossed out, initialed, dated and the reason for discarding indicated using the MS Word “Track Change” feature.

### **Maintenance and Storage of Electronic Record**

- Electronic records and data files are backed up on a regular basis to safeguard against the loss of information due to equipment malfunctions or human error, and should be performed in accordance with the requirement of the MDSAP IT Portal. Documents such as audit reports, archived procedures, reviews, corrective actions, etc., are filed and stored using the IT

MDSAP QMS Control of Quality Records Procedure	Document No.: MDSAP QMS P0007.004	Page 5 of 7
--	--------------------------------------	-------------

Portal.

- External labels for example for storage media are labeled to facilitate accurate filing and retrieval of electronic records and should follow the process described in the MDSAP QMS P0002 Document Control and Approval Procedure.
- All electronic records (regardless of physical format or electronic/computer file format) shall be scheduled, managed and dispositioned in accordance with approved retention schedules. MDSAP teams shall use system controls which ensure that its electronics records are authentic, not altered or tampered with, auditable and produced in systems which utilize security measures to ensure integrity. Security controls are in place to limit risk, magnitude of loss, misuse, or unauthorized release of information.
- Electronic records and data files must be backed up on a routine basis to preserve in case of equipment failure or catastrophe and to safeguard against the loss of information.

### **Access**

- There is restricted access to all records to prevent unauthorized use and amending of information
- Records are secured at all times, and
- Electronic records should have password or file protection, or read-only capabilities as described in the MDSAP QMS P0002 Document Control and Approval Procedure.
- MDSAP teams shall comply with all access control standards (which might be different per location), procedures, and requirements pertaining to the systems being used. Act ethically, take initiative, and accept responsibility for safeguarding information resources under their control. Keep alert to threats and vulnerabilities, stay abreast of security policies and issues, and report all know or suspected incident to the appropriate contact

### **Record Retention**

- Each MDSAP site should regularly review the current records control schedules and, when required, propose updates to current record control schedules as the needs evolve, and draft records control schedules for new program's records. The retention period will not be less than five years or as governed by specific regulation and/or policy at that specific site. For example MDSAP-FDA may follow record control schedules as specified in 36 CFR 1228 and/or FDA Administrative and Programmatic Records Control Schedule:  
<http://inside.fda.gov:9003/it/RecordsManagement/RetentionInstructions/ucm155729.htm>  
or/NARA's General Records Schedules: <http://www.archives.gov/records-mgmt/grs/>

### **Disposal of Records**

Uncontrolled when printed:  
For the most current copy, contact [MDSAP@fda.hhs.gov](mailto:MDSAP@fda.hhs.gov)

MDSAP QMS Control of Quality Records Procedure	Document No.: MDSAP QMS P0007.004	Page 6 of 7
--	--------------------------------------	-------------

- After the retention period is completed, records may be destroyed or if necessary transferred to an appropriate storage facility such as for MDSAP FDA to the National Archives and Records Administration (NARA), or Federal Records Center or to a records retention facility meeting the requirements of 36 CFR Part 1228 Subpart K or 3 disposal, if authorized. Each MDSAP site should follow their own regulations and policy for disposal of records.

## 6. Forms

MDSAP QMS F0007.1 – Control of Quality Records Flowchart

## 7. Reference Documents

MDSAP QMS P0002 – Document Control and Approval Procedure  
 ISO/IEC 17011 – Conformity Assessment –General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies  
 ISO/IEC 17021 – Conformity Assessment – Requirements for Bodies providing Audit and Certification of Management Systems  
 IMDRF/MDSAP WG/N3:2016 – Requirements for Medical Devices Auditing Organizations for Regulatory Authority Recognition

## 8. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2013-07-15	Initial Release	Liliane Brown, FDA
002	2015-09-22	On page 3; Japan was added to the site which is applicable to this process.	Liliane Brown, FDA
003	2016-07-28	ON PAGE 4: Section Procedure, sub-section Record Maintenance; first paragraph 6 <sup>th</sup> bullet – preventive actins was updated to preventive actions	Liliane Brown, FDA
004	2016-10-11	Changes were made throughout the document to reflect ISO 9001:2015 revisions	Liliane Brown. FDA

MDSAP QMS Control of Quality Records Procedure	Document No.: MDSAP QMS P0007.004	Page 7 of 7
--	--------------------------------------	-------------

Version 004  
Approval

Approved: Signature on file \_\_\_\_\_ Date: 2016-10-24 \_\_\_\_\_  
CHAIR, MDSAP RAC